IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

THE UNITED STATES OF AMERICA, THE STATE OF CALIFORNIA, THE STATE OF DELAWARE, THE STATE OF FLORIDA, THE STATE OF GEORGIA, THE STATE OF HAWAII, THE STATE OF ILLINOIS, THE STATE OF INDIANA, THE STATE OF LOUISIANA, THE STATE OF MICHIGAN, THE STATE OF MONTANA, THE STATE OF NEVADA, THE STATE OF NEW JERSEY, THE STATE OF NEW MEXICO, THE STATE OF NEW YORK, THE STATE OF OKLAHOMA, THE STATE OF RHODE ISLAND, THE STATE OF TENNESSEE, THE STATE OF TEXAS, THE STATE OF WISCONSIN, THE COMMONWEALTH OF MASSACHUSETTS, THE COMMONWEALTH OF VIRGINIA, THE DISTRICT OF COLUMBIA, THE CITY OF CHICAGO and THE CITY OF NEW YORK, ex rel. STEVE GREENFIELD, Plaintiffs, vs. Medco Health Systems, Inc., Accredo Health Group, Inc., and Hemophilia Health Services, Inc. Defendants.	§	**Docket No. 1:12- CV - 522** **THIRD AMENDED QUI TAM COMPLAINT**

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RELATOR'S THIRD AMENDED QUI TAM COMPLAINT

I. INTRODUCTION

1. Plaintiff/Relator hereby files this Third Amended Complaint[1] (hereinafter the "Complaint") pursuant to Section 31 U.S.C. Title 3729 and 3730, under which a civil action may be brought for violations of 31 U.S.C. Section 3729 regarding false claims on behalf of the United States Government, and the various States listed herein under their own False Claims Act. The purpose of this amendment is to re-file his claims in a Third Amended Complaint consistent with the direction provided by the Court in its's Opinion (Doc # 42, page 25).

2. Defendants are Medco Health Systems, Inc. (Medco), it's subsidiary Accredo Health Group, Inc. (Accredo) and Hemophilia Health Services, Inc. (HHS). Medco is a health care company that provides, inter alia, pharmacy services. Accredo provides specialty pharmacy and related services for patients with certain complex and chronic conditions. HHS provides hemophilia therapy management programs in the United States.

3. Relator alleges that Medco, through it's subsidiaries, Accredo and HHS.

[1] The original Complaint was filed on January 27, 2012 under Seal pursuant to § 31 U.S.C. Title 3729. On December 28, 2012 the United States declined to intervene and on January 7, 2013, the Court unsealed the Complaint. The First Amended Complaint was filed in February 2013 and served on all Defendants. The parties have consented to the filing of a Second Amended Complaint to clarify certain unintended factual misstatements. Thereafter, Defendant filed a Motion to Dismiss (MTD) which the District Court granted, dismissing the Second Amended Complaint without prejudice, but granting Plaintiff thirty (30) days to re-file his claims in a Third Amended Complaint consistent with the direction provided by the Court in its's Opinion (Doc # 42, page 25)

(collectively "Defendants" or the "Company") violated the Anti-Kickback Statute[2] ("AKA") in two primary ways.

A. Renumeration Disguised as Charitable Contributions

4. First, the Company offers and gives substantial inducements and funding to 501(c)(3) charitable organizations that support hemophilia patients, disguised as "charitable donations[3]" when, in fact, such donations are prohibited 'remuneration" under the AKS because they are intended to induce referrals of hemophilia patients who receive benefits from Federal health care programs. These contributions, which total in the millions of dollars, are made by the Company based on its financial interest and obtaining a "*return on their investment.*[4]"

5. These "charitable contributions" are connected to referrals in that Medco and it's subsidiaries are provided information so they can correlate the amount or frequency of its donations with the amount or frequency of referrals its receives by and through the charities. The practice in New Jersey is a model and example of how Medco connects their "charitable contributions" to referrals, making them illegal kickbacks throughout the country. The first scheme is for Medco, through Accredo, to make their contribution to Hemophilia Services, Inc. (HSI) which is a 501(c)(3) charitable organization established to provide insurance to qualified individuals. HSI is

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[2] The Medicare, Medicaid and Anti-Kickback Act ("AKA") 42 U.S.C. §1320a-7b(b)

[3] As an example, see Exhibit C attached hereto which consists of a spreadsheet for Medco 2009 *"charitable contributions"* that is itemized by State, payee organization, stated purpose of the contribution, amount, and when it was delivered. The total budget amount for 2009 was $1,802,200.00 dollars

[4] See Exhibits J, K and L-1, L-2, L-3 and L-4

an affiliate of Hemophilia Association of New Jersey (HANJ), which is also a 501(c)(3) charitable organization.

6. HANJ and HSI (as do other Hemophilia State Associations and charities) have significant influence with designated Hemophilia Treatment Centers (HTC), it's member/patients, as well as State Regulatory authorities (in New Jersey, the Department of Insurance and Banking). The influence extends to approving or being able to "block" applications to be a Licensed Provider, making grants to HTC's and to recommending or guiding patients to providers as described herein.

7. In New Jersey, a common practice is for HSI to use Medco's contribution to purchase insurance through New Jersey Horizon Health and other insurers. That patient, in turn, is guided to use Medco or its affiliates as its provider. The second scheme involves HSI using the Medco contributions for "grants" to the designated Hemophilia Treatment Centers (HTC) in New Jersey.

8. In turn, the HTC's make referrals of their patients to Medco or its affiliates to use them as their provider. Medco, Accredo and HHS use this ring of influence by providing renumeration, disguised as "*contributions*" for the primary purpose and with the intent of soliciting and receiving referrals for it to sell "factor" product to hemophilia patients, many of whom are beneficiaries of a Federal Health Care Program.

B. Expensive Gifts to Patients as Renumeration

9. Second, in addition to the above use of "charitable contributions" as kickbacks or illegal renumeration, Defendants, in order to keep the hemophilia patients that have been referred, have also violated the AKS by offering and/or providing its

hemophilia patients who are Medicare or Medicaid beneficiaries *"remuneration"* that it *"knows or should know is likely to influence the beneficiary's selection of a particular provider."*

10. The Office of Inspector General of the Department of Health and Human Services (HHS-OIG) has interpreted the prohibition to permit Medicare or Medicaid providers to offer beneficiaries only 'inexpensive gifts" (other than cash or cash equivalents) or services without violating the statute. For enforcement purposes, inexpensive gifts or services are those that have a retail value of no more than $10 individually, and no more than $50 in the aggregate annually per patient. Defendants representatives routinely and systematically provide gifts that exceed the permitted limit to keep hemophilia patients receiving specialty pharmaceuticals, which include expensive meals and other gifts. This practice, as described herein, is a common and regular business practice with Medco's specialty pharmaceutical patients, including hemophilia patients, throughout every region of the Country that occurs thousands of times during the course of a year and totals hundreds of thousands of dollars each year.

11. The patient population of specialty pharmaceutical patients, including hemophilia patients is a limited population, but the care for this condition is extraordinarily expensive. A substantial portion of this cost is borne by Federal Health Care programs. The market place for providers is competitive but also limited. The practices of Medco described herein corrupts this market and results in excess cost to the federal fisc.

12. The allegations set forth in this Complaint are based upon the direct and independent knowledge of Relator, as an insider of the Company. Relator has not based his allegations upon any prior public disclosure of the wrongful actions or transactions. This lawsuit is based solely on information and knowledge obtained by Relator in his position as an insider.

13. If a public disclosure of Relator's allegations was made prior to filing of this suit, which Relator expressly denies, Relator is nevertheless the original source of any such allegations or disclosures. Prior to filing this suit, Relator made full and complete disclosure of all material information known to him to agents of the United States government and of the States.

II. THE PARTIES

A. The Relator - Steve Greenfield

14. Relator is Steve Greenfield who is an experienced and successful sales and marketing executive with a wide range of experience with Fortune 100 companies as well as start up companies in the health care industry. Since 2009 Relator has been with Defendants as an Area Vice president of Accredo covering the eastern United States which represents 400 million in sales. A copy of his resume is attached hereto as Exhibit A-1.

15. It was in this capacity that Relator learned of the fraudulent practices that Defendants were and are engaging in throughout his region and the rest of the country, to induce referrals from other providers and maintain and ensure that its specialty pharmaceutical patients, including hemophilia patients continue to purchase their

products through Defendants.

B. Defendants

1. MEDCO HEALTH SOLUTIONS, INC

16. Medco Health Solutions, Inc., a Delaware corporation ("Medco"), has principal office located at 100 Parsons Pond Drive, Franklin Lakes, NJ, 07417-2603. Medco is a healthcare company that provides pharmacy services for private and public employers, health plans, labor unions and government agencies of all sizes, and for individuals served by Medicare Part D Prescription Drug Plans.

17. Medco offers therapy management programs using Medco Specialist Pharmacists to treat certain chronic conditions, including Accredo Health Group, Medco's Specialty Pharmacy. Medco contracts with payors, retail pharmacies, physicians, pharmaceutical manufacturers, CMS for Medicare, and, particularly in Specialty Pharmacy, contracts with other third-party payors such as health insurers, and state Medicaid agencies.

2. ACCREDO HEALTH GROUP, INC.

18. Accredo Health Group, Inc., headquartered in Memphis, Tennessee provides specialty pharmacy and related services for patients with certain complex and chronic conditions. Accredo is a wholly owned subsidiary of Medco Health Solutions, Inc. and is the nation's largest specialty pharmacy based on reported revenues. Specialty pharmacy drugs are generally manufactured by biopharmaceutical or biotechnology companies, and tend to be more expensive than traditional medicines

and can cost as much as several hundred thousand dollars up to millions per patient per year.

19. These specialty drugs are often infusible or injectable and require special handling, temperature control and ancillary equipment, as well as a higher level of individualized patient care as compared to traditional medicines. The company focuses on injectable and oral drugs. It offers overnight delivery of drugs to treat hemophilia, pulmonary arterial hypertension, respiratory syncytial virus, multiple sclerosis, growth hormone deficiency, gaucher disease, and other chronic conditions.

20. Accredo Health Group provides therapy management services to patients taking specialty medicines to treat complex or chronic conditions. Accredo Health Group focuses on dispensing infused, injectable, inhaled, and oral drugs that require a higher level of patient services and support compared to what typically is available from traditional pharmacies. Many specialty drugs have FDA safety and monitoring requirements. Accredo Health Group's therapy teams may include specialty-trained pharmacists, registered nurses and patient service representatives. Patients receive counseling and education services that include, but are not limited to, training on how to self-administer specialty pharmacy medications, advice on how to cope with potential side-effects, and access to clinical resources that are available around the clock to assist patients in managing critical aspects of care.

21. Accredo Health Group dispenses up to a 90-day supply of specialty medications directly to the patient, the patient's physician, or an infusion center with packaging and temperature-controlled handling and shipping as appropriate to maintain

product integrity. The shipment may contain ancillary supplies required for administration. A majority of products are dispensed and shipped from three specialty pharmacy facilities.

22. Accredo's Therapeutic Resource Centers are segmented by therapy and provide targeted therapy management programs for the following therapeutic areas: Rheumatoid arthritis, Multiple sclerosis, Oncology, Hepatitis C, Immune disorders, Pulmonary arterial hypertension, and Hemophilia. Other specialty therapies with dedicated care teams (RSV, growth deficiencies, etc.).

23. Craig W. Mears was President of Hemophilia Health Services at Accredo Health Group, Inc. from August 2007 until October 2011. Mr. Mears provides overall management, direction, and leadership for Accredo Health Group. He has been involved with the bleeding disorders community for over 16 years. His successor is now Bruce Scott. Prior to this Scott was President of Critical Care Systems which was acquired by Accredo in or about 2008.

24. The organizational structure and management team are described in the attached Exhibits marked as Exhibit A-2 through A-7 as follows:

Exhibit A-2 - organizational charts for Accredo and it's internal divisions;

Exhibit A-3 - Contact list of vice presidents who are Regional Business Leaders;

Exhibit A-4 - Schedule and Directory of Branch Operations Personnel and managers with contact information;

Exhibit A-5 - Schedule of Sales Representatives with contact information;

Exhibit A-6 - Map delineating breakout of regional structure of Accredo's Infusion business.

Exhibit A-7 - Memorandum dated October 2011 from Bruce Scott reorganizing and re-aligning Infusion Services that include job title and descriptions.

3. HEMOPHILIA HEALTH SERVICES, INC.

25. Hemophilia Health Services, Inc. (HHS) provides hemophilia therapy management programs in the United States. It offers bleeding disorders therapy management, and drug therapies. Hemophilia Health Services, Inc. was founded in 1990 and is based in Nashville, Tennessee. Hemophilia Health Services, Inc. operates as a subsidiary of Accredo Health Group, Inc. HHS principal office is located at 201 Great Circle Road, Nashville, TN 37228.

C. The Hemophilia Public Charities in New Jersey

1. HEMOPHILIA ASSOCIATION of NEW JERSEY, INC. (HANJ)

26. The Hemophilia Association of New Jersey (HANJ) was founded in August 1971. It is a 501(c)(3) organization and has tax exempt status with an employer ID number of 22-1964188. HANJ offers assistance to persons with hemophilia and their families from the office located in East Brunswick, New Jersey. HANJ is located at 197 Route 18 South, Suite 206, North East Brunswick, NJ 08816. HANJ funds, via grants, referral entities (such as the HTC's) and makes recommendations to the State for competitive providers.

27. HANJ lists on its website four (4) HSI "approved vendors". In addition to

HHS, they are as follows:

a. Coram Hemophilia Services (CHS) is a specialty program of Coram Specialty Infusion Services, an Apria Healthcare company, and a provider of home infusion and pharmacy services. It has more than 75 company-owned branch locations nationwide, and nearly 1,000 specialty pharmacists and home infusion nurses on staff. ,

b. BioScrip is a publicly traded company that provides comprehensive pharmaceutical care solutions. It focuses its services in four core areas; specialty medications delivered via mail, Pharmacy Benefit Management, Community Pharmacies and Infusion Services. BioScrip also offers Pharmacy Benefit Management programs that include pharmacy network management. and sophisticated reporting capabilities that deliver improved clinical and economic outcomes. In addition they have 33 retail locations in 25 major metropolitan markets across the US, to provide nationwide capabilities within a high-touch community based environment.

c. Bleeding Disorders Resources Network, LLC is located in New Jersey at South Corporate Drive, 2nd Fl, Suite D, Riverdale, NJ 07457.

2. HEMOPHILIA SERVICES, INC.

28. HANJ formed Hemophilia Services, Inc. (HSI). It is a 501(c)(3) organization and has tax exempt status with an employer ID number of 22-3189183. By working together with the treatment centers, insurers and participating homecare vendors, HSI provides case management services for the New Jersey Hemophilia population.

29. The HSI approved vendors are (i) Bioscrip Infusion Services, (ii) Hemophilia

Health Services, (iii) Bleeding Disorders Resource Network and (iv) CORAM Hemophilia Services. Elena Bostick is the Executive Director of HSI and HANJ.

D. The United States and the State Plaintiffs

30. The United States of America is a real party in interest pursuant to the FCA, and specifically on behalf of two United States' agencies: the Department of Health and Human Services ("HHS"), and particularly its Centers for Medicare & Medicaid Services ("CMS"), formerly the Health Care Financing Administration, as CMS administers the Medicare and Medicaid programs which the Defendants' unlawful and fraudulent actions harmed.

31. The States of California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Michigan, Montana, Nevada, New Jersey, New Mexico, New York, Oklahoma, Rhode Island, Tennessee, Texas and Wisconsin, together with the Commonwealths of Massachusetts and Virginia, the District of Columbia, and the Cities of Chicago and New York are real parties in interest pursuant to each of their State FCAs, listed above, on behalf of each of their Medicaid agencies, which administer and fund each of said governmental entity's portion of Medicaid expenditures, as further described below, and which Defendants' unlawful and fraudulent actions harmed.

III. JURISDICTION

32. This action arises under the FCA, 31 U.S.C. §§3729 et seq., and the Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§1331 and 1345.

33. This Court also has supplemental jurisdiction over the claims brought by Relator on behalf of the States under their state FCAs, pursuant to 28 U.S.C. §1367(a) and 31 U.S.C. §3732(b), and the individual state claims brought by Relator pursuant to 28 U.S.C. §1367(a).

IV. VENUE

34. Venue in this district is proper pursuant to 31 U.S.C. §3732(a) and 28 U.S.C. §1391(b) and © since one or more of the Defendants transact business in this district and/or one or more of the acts at issue occurred in this district.

V. FEDERAL AND STATE LAWS

A. The Federal Health Care Programs

35. The Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §1395 et seq., (hereinafter "Medicare") is a Health Insurance Program administered by the Government of the United States that is funded by taxpayer revenue. The program is overseen by the United States Department of Health and Human Services. Medicare is a health insurance program that provides for the payment of prescription drugs, hospital services, medical services and durable medical equipment to persons over sixty-five (65) years of age and others that qualify under the terms and conditions of the Medicare Program.

36. The Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. § 1396-1396v (hereafter "Medicaid"), is a Health Insurance Program administered by the Government of the United States and the various individual States and is funded by

State and Federal taxpayer revenue. The Medicaid Program is overseen by the United States Department of Health and Human Services. Medicaid was designed to assist participating states in providing medical services, durable medical equipment and prescription drugs to financially needy individuals that qualify for Medicaid.

37. The Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS") (now known as "TRICARE"), 10 U.S.C. secs. 1071-1106, provides benefits for health care services furnished by civilian providers, physicians, and suppliers to members of the Uniformed Services and to spouses and children of active duty, retired and deceased members. The program is administered by the Department of Defense and funded by the Federal Government. CHAMPUS pays for, among other items and services, prescription drugs for its beneficiaries.

38. The federal government, through its Departments of Defense and Veterans Affairs, Bureau of Prisons, Native and American Indian Health Services, and Public Health Service maintains and operates medical facilities including hospitals, and receives and uses federal funds to purchase prescription drugs for patients treated at such facilities and otherwise.

39. The Federal Employees Health Benefits Program ("FEHBP") provides health care benefits for qualified federal employees and their dependents. It pays for, among other items and services, prescription drugs for its beneficiaries. (Together these programs described above shall be referred to as "Federal Health Care Programs" or "Government Health Care Programs").

B. The False Claims Act

40. The Federal FCA, 31 U.S.C. § 3729(a)(1)[5] makes "knowingly" presenting or causing to be presented to the United States any false or fraudulent claim for payment, a violation of federal law for which the United States may recover three times the amount of the damages the government sustains and a civil monetary penalty of between $5,000 and $10,000 per claim ($5,500 and $11,000 for claims made on or after September 29, 1999).

41. The Federal FCA, 31 U.S.C. § 3729(a)(2) makes "knowingly" making, using, or causing to be used or made, a false record or statement to get a false or fraudulent claim paid or approved by the Government, a violation of federal law for which the United States may recover three times the amount of the damages the Government sustains and a civil monetary penalty of between $5,000 and $10,000 per claim ($5,500 and $11,000 for claims made on or after September 29, 1999).

42. The Federal FCA, 31 U.S.C. sec. 3729(a)(3) makes any person, who conspires to defraud the United States by getting a false or fraudulent claim allowed or paid, liable for three times the amount of the damages the Government sustains and a civil monetary penalty of between $5,000 and $10,000 per claim ($5,500 and $11,000 for claims made on or after September 29, 1999).

43. The Federal FCA defines a "claim" to include any request or demand,

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[5] On May 22, 2009, the Fraud Enforcement and Recovery Act (FERA) was enacted into law which, inter alia, amended the False Claims Act. Part of the amendment renumbered ceratin sections. Under FERA, effective 5/22/09 3729(a)(1) became 3729(A)(1). Likewise, 3729(a)(2) became 3729(A)(2) and 3729(a)(3) became 3729(A)(3) . Since the allegations include a time period before and after 5/22/09, references are to be applicable sections

whether under contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested.

C. The State False Claims Acts

44. As specified above, the States have enacted State FCAs, false claims acts similar to the federal FCA, permitting a private person such as Relator to bring suit to recover on behalf of each of the States from persons that knowingly submit false claims to the State(s) or engage in related misconduct, and providing for awards to a private person bringing the action if the State(s) prevail in the actions

45. As set forth below, several states have passed False Claims Act legislation, which in most instances closely tracks the Federal FCA: California False Claims Act, Cal. Govt. Code § 12650 *et seq.*, Delaware False Claims and Reporting Act, Del. Code Ann. Tit. 6, § 1201 *et seq.*, District of Columbia Procurement Reform Amendment Act, D.C. Code § 2-308.13 *et seq.*, Florida False Claims Act, Fla. Stat. § 68.081 *et seq.*, Georgia False Medicaid Claims Act, 49 Ga. Code Ann. Chapter 4 at 49-4-168, *et seq.*, Hawaii False Claims Act, Haw. Rev. Stat. § 661-21 *et seq.*, Illinois Whistle blower Reward and Protection Act, 740 Ill. Comp. Stat. § 175/1 *et seq.*, Indiana False Claims and Whistle blower Protection Act, IC 5-11-5.5, Louisiana Medical Assistance Programs Integrity Law, 46 La. Rev. Stat. c. 3, sec. 437.1 *et seq.*, Massachusetts False Claims Act, Mass. Gen. Laws Ch. 12, § 5A *et seq.*, Michigan Medicaid False Claims Act, MI ST

Ch. 400, Nevada False Claims Act, Nev. Rev. Stat. § 357.010 *et seq.*, New Mexico Medicaid False Claims Act, 2004, New Mexico Laws Ch. 49 (H.B. 468), New York False Claims Act 2007, New York Laws 58, section 39, article 13, section 189 *et seq.*, Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 *et seq.*, Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code § 36.001 *et seq.*, and Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1 *et seq.* These State False Claims Acts apply to the state portion of Medicaid fraud losses caused by false Medicaid claims to the joint federal-state funded Medicaid program. Each of the statutes listed above contains *qui tam* provisions governing, *inter alia*, a relator's right to claim a share of the State's recovery.

D. The Anti-Kickback Statute

46. The Medicare, Medicaid and Anti-Kickback Act ("AKA") 42 U.S.C. §1320a-7b(b), makes it illegal to:

> *offer,* receive, or solicit *any remuneration*, kickback, bribe, or rebate, whether directly or indirectly, overtly or covertly, in cash or in kind, to or from any person in order *to induce such person to purchase*, lease, or order, or to arrange for or recommend the purchasing, leasing, or ordering of *any good, service, or item for which payment may be made in whole or in part under a Federal Health Care Program.*

Many States have similar laws pertaining to the Medicaid program.

The AKA has certain safe harbors as follows:

> (3) Paragraphs (1) and (2) shall not apply to–

(A) *a discount or other reduction in price obtained by a provider of services or*

other entity under a Federal health care program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program; [*emphasis added*]

(B) any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services;

© any amount paid by a vendor of goods or services to a person authorized to act as a purchasing agent for a group of individuals or entities who are furnishing services reimbursed under a Federal health care program if--

(i) the person has a written contract, with each such individual or entity, which specifies the amount to be paid the person, which amount may be a fixed amount or a fixed percentage of the value of the purchases made by each such individual or entity under the contract, and

(ii) in the case of an entity that is a provider of services (as defined in section 1395x(u) of this title), the person discloses (in such form and manner as the Secretary requires) to the entity and, upon request, to the Secretary the amount received from each such vendor with respect to purchases made by or on behalf of the entity;

(D) a waiver of any coinsurance under part B of subchapter XVIII of this chapter by a Federally qualified health care center with respect to an individual who qualifies for subsidized services under a provision of the Public Health Service Act [42 U.S.C.A. § 201 et seq.];

(E) any payment practice specified by the Secretary in regulations promulgated pursuant to section 14(a) of the Medicare and Medicaid Patient and Program Protection Act of 1987 or in regulations under section 1395w-104(e)(6) of this title;

(F) any remuneration between an organization and an individual or entity providing items or services, or a combination thereof, pursuant to a written agreement between the organization and the individual or entity if the organization is an eligible organization under section 1395mm of this title or if the written agreement, through a risk-sharing arrangement, places the individual or entity at substantial financial risk for the cost or utilization of the items or

services, or a combination thereof, which the individual or entity is obligated to provide;

(G) the waiver or reduction by pharmacies (including pharmacies of the Indian Health Service, Indian tribes, tribal organizations, and urban Indian organizations) of any cost-sharing imposed under part D of subchapter XVIII of this chapter, if the conditions described in clauses (i) through (iii) of section 1320a-7a(i)(6)(A) of this title are met with respect to the waiver or reduction (except that, in the case of such a waiver or reduction on behalf of a subsidy eligible individual (as defined in section 1395w-114(a)(3) of this title), section 1320a-7a(i)(6)(A) of this title shall be applied without regard to clauses (ii) and (iii) of that section);

(H) any remuneration between a federally qualified health center (or an entity controlled by such a health center) and an MA organization pursuant to a written agreement described in section 1395w-23(a)(4) of this title;

(I) any remuneration between a health center entity described under clause (i) or (ii) of section 1396d(l)(2)(B) of this title and any individual or entity providing goods, items, services, donations, loans, or a combination thereof, to such health center entity pursuant to a contract, lease, grant, loan, or other agreement, if such agreement contributes to the ability of the health center entity to maintain or increase the availability, or enhance the quality, of services provided to a medically under served population served by the health center entity; and

(J) a discount in the price of an applicable drug (as defined in paragraph (2) of section 1395w-114a(g) of this title) of a manufacturer that is furnished to an applicable beneficiary (as defined in paragraph (1) of such section) under the Medicare coverage gap discount program under section 1395w-114a of this title.

None of the actions, practices or policies of Defendants described herein falls within any of these "safe harbors."

E. Relevant HHS-OIG Advisory Opinions

47. Notwithstanding the above, OIG's position is that section 1128A(a)(5) does not necessarily prevent valuable services or other remuneration from being furnished to

financially needy beneficiaries by an independent entity, such as a patient advocacy group, even if the benefits are funded by providers, so long as the independent entity makes an independent determination of need and the beneficiary's receipt of the remuneration does not depend, directly or indirectly, on the beneficiary's use of any particular provider.

48. An example of such an arrangement, and how the OIG interprets the Rules involving donations to charities by providers is *Advisory Opinion No. 10-19*[6] set forth *(substantially in its entirety)* and described below. The opinion sets out the parameters and conditions under which OIG provides the Advisory Opinion, the factual background on which it based as well as a legal analysis that sets out the standards under which such "donations" must meet in order to avoid a violation of the AKS.

1. OIG Advisory Opinion No. 10-19

> *OIG was asked to provide an Advisory Opinion regarding a proposed arrangement for a non-profit charitable organization to receive donations of cash and durable medical equipment ("DME") from pharmaceutical manufacturers, DME suppliers and others, to provide funding grants and DME to entities that serve individuals suffering from coagulation disorders, and to provide DME directly to certain financially needy individuals (the "Proposed Arrangement"). This Advisory Opinion is being discussed and disclosed because of similarities to the case at hand. The standards set out by the OIG is instructive and relevant to the allegations by the Relator herein with respect to whether Defendants actions violate the civil monetary penalty provision at section 1128A(a)(5) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act, and the Federal anti-kickback statute.*

[6] A copy of such Advisory opinion is attached hereto as Exhibit B.

While OIG concluded that, based on the facts certified to in request for an advisory opinion, it would not impose administrative sanctions on Requestor, it cautioned that the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce or reward referrals of Federal health care program business were present.

FACTUAL BACKGROUND

The "Council" is a non-profit public benefit corporation organized to provide education, information, and psychological services and advocacy to individuals with hemophilia in a "State". The members of the Council are: [names redacted], each of which serves similar purposes to the Council in different regions of the State (the "Member Organizations"). Collectively, the Council and its Member Organizations will be designated in this opinion as the "Requestors." The Requestors propose to form the [name redacted], an independent, non-profit, tax-exempt charitable organization (the "Foundation") that would provide: (i) financial grants to entities that provide services to individuals suffering from coagulation disorders; and (ii) DME to such entities as well as directly to individuals suffering from coagulation disorders.

The entities that would receive financial grants would include the Member Organizations and other non-profit, tax-exempt organizations serving the needs of persons with coagulation disorders, as well as Hemophilia Treatment Centers ("HTCs"). HTCs are Federally designated centers housed in university-based tertiary care hospitals that provide comprehensive care to patients with hemophilia. HTCs are organized by region, and the Foundation would provide assistance to HTCs within the region that includes the State. The Requestors estimate that only approximately 10% of grants would be allocated to HTCs.

The Requestors anticipate that Foundation donors would include pharmaceutical manufacturers that make drugs for the treatment of coagulation disorders, pharmacies dispensing such drugs, and providers that furnish items and services to individuals who have coagulation disorders (collectively, the "Coagulation Disorder Industry"). Donors would also include the general public.

Donors would not be permitted to impose any restrictions

on use of their contributions, except that donors would be permitted to earmark contributions to be used for a specific coagulation disorder. Donors would not be able to direct to whom such contributions should be awarded. Donors would not be told the specific use to which their contributions were or would be put, but they would have access to quarterly reports disclosing the recipients of awards granted by the Foundation.

Similarly, recipients of funding grants would not be told the identity of the particular donor that contributed to an award, but quarterly reports issued by the Foundation would disclose the names of donors; the amounts contributed to the Foundation; and for donors that make public filings, the percentage that identifies the relation such contribution has to the operations of the donor.

The Requestors have certified that the Foundation would not be subject to control, whether directly or indirectly, by any donor. The Foundation would be governed by a Board of Directors (the "Board"). The bylaws will provide that individuals who derive any financial benefit, directly or indirectly, from the Coagulation Disorder Industry would not be permitted to serve on the Board. Donors to the Foundation and any individual affiliated with a donor in any way, including as an employee, agent, officer, shareholder, or contractor of a donor, would be barred from serving on its Board. Similarly, no Board member would be affiliated in any way, including as an employee, agent, officer, shareholder, or contractor, with a manufacturer of pharmaceutical drugs, particularly those used in the treatment of coagulation disorders; wholesalers of such drugs; pharmacies dispensing such drugs; and providers furnishing services and products that are reimbursable by Federal health care programs to individuals suffering from coagulation disorders.

Four of the members of the Board would be non-voting ex officio members who would be appointed by the governing bodies of the four Member Organizations. These non-voting ex officio Board members could be any officer or member of the Member Organizations or a member of the public so long as they are not donors to the Foundation or affiliated with a donor. The elected members of the Board who are permitted to vote would be nominated by a nominating committee consisting of

the members of the boards of directors of the Member Organizations. The individuals that participate in the nominating committee would not be affiliated in any way, including as an employee, agent, officer, shareholder, or contractor, with a manufacturer of pharmaceutical drugs, particularly those used in the treatment of coagulation disorders; wholesalers of such drugs; pharmacies dispensing such drugs; and health care providers furnishing services and products that are reimbursable by Federal health care programs to individuals suffering from coagulation disorders. The voting members of the Board would elect the subsequent class of voting directors. Board members, officers, and other staff of the Foundation would not make any referrals to physicians, suppliers, or other health care providers and would not provide any recommendations with regard to any particular drug, supply, or item of DME used to treat coagulation disorders. Moreover, neither the Foundation nor the Member Organizations provide health care services or bill Federal health care programs.

The Requestors have certified that the Foundation would operate with absolute, independent and autonomous discretion as to the award of assistance, and that it would award assistance without regard to any donor's financial interest and without regard to whether the recipient refers patients for a donor's products, services, or supplies. The Requestors have certified that neither the Foundation nor any of its Board members (whether voting or non-voting) or Member Organizations would provide donors with any information that would facilitate the donor in correlating the amount or frequency of its donations with the amount or frequency of referrals of or use of its products, services, or supplies.

Financial Grants to Entities

The Foundation would distribute financial assistance to: (1) non-profit organizations serving the needs of persons with coagulation disorders that meet the criteria to be designated as an Internal Revenue Code Section 501(c)(3) public charity, including Member Organizations; and (2) Federally funded HTCs in the Foundation's region, as long as the HTC does not have a 340B program. (Together, these two types of entities will be designated in this opinion as "Qualified Entities.") Individuals would not be eligible to apply to the Foundation for financial grants. Qualified Entities

(including the Member Organizations) could apply to the Foundation to receive funding grants for the provision of services that support individuals and families affected by coagulation disorders. Specifically, grants would be awarded only for operational purposes, such as capital support for construction of facilities used to provide services to individuals and families affected by coagulation disorders; general and operating expenses of the recipient; program development, which may include funding for staff positions or fellowships at an HTC (but not for salaries for treating physicians); technical assistance to improve recipient organizational and internal program operations; and to fund ancillary services needed by hemophilia patients such as transportation expenses for treatment and housing during treatment. Grants would not be available to fund health care items or services or to subsidize cost-sharing obligations of beneficiaries.

The Foundation would disseminate information about the availability of grants through various mediums, including fliers, pamphlets, relationships with the Requestors, and through health care facilities. Qualified Entities would apply for grants by participating in a formal Request for Assistance ("RFA") process. Qualified Entities would submit a RFA to the Foundation's Board, and the Board would award financial grants based on objective criteria unrelated to the use of any donor's products or services. The Board would designate a panel comprised of individuals with professional expertise or personal knowledge of coagulation disorders to make non-binding recommendations to the Board with regard to an RFA. No employee, agent, officer, shareholder, or contractor of an applicant or donor would be permitted to serve on the advisory panel. The Foundation would maintain a conflict of interest policy to assist the Board in determining whether a conflict exists with respect to a person's consideration of a particular RFA. If a conflict existed, the Board would exclude such person from considering that application. After receiving the panel's recommendation, the Board would determine which entities would be awarded a grant and the amount of such grant by a two-thirds vote in favor of the award by voting Board members.

The Foundation would develop a contribution acceptance policy to ensure that the decision-making of any ultimate recipient is insulated from information that could influence their choices. The policy would indicate that receipt of the grant is not dependent on

use of any particular product or service of a donor and would reiterate that recipients would not be permitted to use the funds for health care items or services; to subsidize Federal health care program beneficiary cost-sharing; or to pass the funds on to other affiliated entities. This policy would require that the recipient use the grant funds only for the operational and administrative purposes for which the grant was awarded. To ensure compliance with this requirement, the Foundation would require the recipient to provide quarterly reports and supporting documentation detailing how the funds are being used. The funds would be distributed in parts on a quarterly basis, and the Foundation would not distribute the next quarter's funds until the quarterly report is received and the recipient confirms that the funds were used only as authorized.

LEGAL ANALYSIS

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir. 1985), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

In the Proposed Arrangement, providers or suppliers of services or items paid for by Federal health care programs would make contributions to a non-profit entity that would, in turn, make grants to other entities that have the ability to refer patients or otherwise direct business to the original donors. The non-profit entity (the Foundation) would also distribute DME, which might be donated or purchased with donated funds, to entities and individual patients.

Charitable donations play an essential role in sustaining and strengthening the health care safety net. We accept that the majority of donors who make contributions to tax-exempt organizations and the majority of tax-exempt entities that solicit or accept donations — including donors and recipients with ongoing business relationships with one another — are motivated by bona fide charitable purposes and a desire to benefit their communities. Substantial numbers of health care providers are non-profit organizations, many of which depend on tax-deductible charitable donations to fund all or part of their operations. A business relationship between a donor and a recipient does not make a tax-deductible donation automatically suspect under the anti-kickback statute. On the other hand, a donation made for the purpose of inducing the recipient to refer Federally-payable business to the donor would violate the anti-kickback statute, regardless of whether the donation was direct or passed through an intermediary. Thus, the Proposed Arrangement requires scrutiny under the anti-kickback statute.

Donors' Cash Contributions to the Foundation

The Proposed Arrangement involves a mechanism by which ***donors to the Foundation are insulated from decisions about the use of their contributions and the recipients of the Foundation's financial grants.*** *Under the circumstances described in the request for an advisory opinion and supplemental submissions, the risk that donations to the Foundation would serve as remuneration for referrals of Federal health care program business is minimal for the following reasons.*

No Donor Control, (direct or Indirect) over Charity*. First, no donor or affiliate of any donor would exert direct or indirect control over the Foundation or its programs. The Foundation would be an independent, nonprofit, tax-exempt charitable organization*

that would have absolute, independent, and autonomous discretion as to the use of donor contributions. Donors or affiliated individuals would not serve on the Board in a voting or non-voting capacity, nor would donors or affiliated individuals serve on panels that make recommendations on grant applications.

Independent Grant Awards By Charity. *Second, the Foundation would award financial grants in a truly independent manner that severs any connection between donors and recipients of grants.*

Awards Made Without Regard To Donor's Financial Interest. *Third, the Foundation would make financial grants without regard to any donor's financial interest and without regard to whether the recipient refers patients for a donor's products, services, or supplies. Donors would not be permitted to impose any restrictions on use of their contributions, except that donors could earmark contributions to be used for a specific coagulation disorder. Donors would not be told the specific use to which their donations were put, nor would recipients of grants be told the identity of the particular donor that contributed to an award.*

No Connection To referrals. *Fourth, neither the Foundation nor any of the Requestors would provide donors with any information that would enable a donor to correlate the amount or frequency of its donations with the amount or frequency of referrals or use of its products, services, or supplies.*

Use of Grant Funds limited. *Fifth, grants would only be awarded for operational and administrative purposes and not for health care items, services, cost-sharing support, or the salaries of physicians. Further, recipients would be required to document how the funds were used, and confirm that they were used for purposes approved in the RFA.*

No referrals By Charity. *Sixth, the Foundation itself would not make any referrals to physicians or other service providers and would not provide any recommendations with regard to any particular drug, supply, or DME item used to treat coagulation disorders. The governing documents of the Foundation would prohibit Board members, officers, and other staff from making any referrals to physicians, suppliers or other health care providers and*

would not provide any recommendations with regard to any particular drug, supply, or item of DME used to treat coagulation disorders. Moreover, the Member Organizations, which have representatives on the Board in a non-voting capacity and may also apply for grant funds, do not provide health care services or bill Federal health care programs.

Based on the above, OIG concluded that there is minimal risk that the cash contributions made by donors to the Foundation would be remuneration to the Foundation or to grant recipients to arrange for referrals.

VI. FACTS AND ALLEGATIONS

. HEMOPHILIA

A. Overview

49. Hemophilia is a rare bleeding disorder in which the blood doesn't clot normally. Individuals with hemophilia may bleed for a longer time than others after an injury and may also may bleed internally, especially in the knees, ankles, and elbows. This bleeding can damage organs and tissues and may be life threatening. Hemophilia usually is inherited. "Inherited" means that the disorder is passed from parents to children through genes.

50. People born with hemophilia have little or no "clotting factor." Clotting factor is a protein needed for normal blood clotting. There are several types of clotting factors. These proteins work with platelets to help the blood clot. Platelets are small blood cell fragments that form in the bone marrow—a sponge-like tissue in the bones. Platelets play a major role in blood clotting. When blood vessels are injured, clotting

factors help platelets stick together to plug cuts and breaks on the vessels and stop bleeding.

51. The two main types of hemophilia are A and B. With hemophilia A, the individual is missing or has low levels of clotting factor VIII (8). About 9 out of 10 people who have hemophilia have type A. With hemophilia B, the individual is missing or has low levels of clotting factor IX (9). Rarely, hemophilia can be acquired. "Acquired" means you aren't born with the disorder, but you develop it during your lifetime. This can happen if your body forms antibodies (proteins) that attack the clotting factors in your bloodstream.

52. Hemophilia can be mild, moderate, or severe, depending on how much clotting factor is in your blood. About 7 out of 10 people who have hemophilia A have the severe form of the disorder. People who don't have hemophilia have a factor VIII activity of 100 percent. People who have severe hemophilia A have a factor VIII activity of less than 1 percent. Hemophilia usually occurs in males. About 1 in 5,000 males are born with hemophilia each year.

53. Approximately 18,000 people are living with hemophilia in the United States[7]. Many of the technological advances in hemophilia treatment have come with high financial price tags. The life-long management of hemophilia places a large financial burden upon individuals and families. In fact, the average annual cost of

[7]http://www.hemophilia.org

clotting factor products can range from $50,000 to $100,000 dollars[8]. In some cases, the cost reaches the millions, annually on a per patient basis.

B. Treatment Therapy

54. The main goal of hemophilia therapy is to keep bleeds from happening or stop a bleed as soon as possible. Factor replacement therapy does exactly what it sounds like it does—replaces the clotting factor that is missing so that there is enough to prevent or stop a bleed. Some bleeds stop after one dose of clotting factor, while others may need several infusions to stop the bleeding. Severe bleeds may even need therapy once or twice a day for several days. The amount of factor needed is based on the severity of the bleed.

55. Doctors prescribe clotting factor therapy on dosing schedules that meet the individual needs of their patients. Treating a bleed when it starts with infusions of clotting factor is called on-demand therapy. Prophylactic (a/k/a "prophy") therapy means that an infusion of clotting factor is given before an event or activity that may cause bleeding. Some bleeds may require medical attention and others may not.

56. For people with hemophilia A, one treatment option is Xyntha® Antihemophilic Factor (Recombinant), Plasma/Albumin-Free, a recombinant factor VIII product. XYNTHA uses a state-of-the-art purification process that's entirely free of

[8]http://www.hemophilia.org

added human and animal materials. XYNTHA Solofuse is the all-in-one reconstitution device.

57. It comes prefilled with diluent and 3000 IU of XYNTHA. XYNTHA is also available in doses of 2000 IU and lower with the Rapid Reconstitution (R2) Kit. XYNTHA has been studied, tested, and proven to work in clinical trials. Xyntha® Antihemophilic Factor (Recombinant), Plasma/Albumin-Free is indicated for the control and prevention of bleeding episodes in patients with hemophilia A (congenital factor VIII deficiency or classic hemophilia) and for surgical prophylaxis in patients with hemophilia A. XYNTHA is an injectable medicine administered by intravenous (IV) infusion. Local irritation may occur when infusing XYNTHA after reconstitution in XYNTHA Solofuse. One treatment option for patients with hemophilia B is BeneFIX® Coagulation Factor IX (Recombinant), the first recombinant factor IX product. HHS acts as a Specialty Pharmacy provider for these and other products.

C. Hemophilia Providers In New Jersey

58. New Jersey statutes and law requires that carriers offering health benefits plans that are managed care plans must contract with a designated health care provider or providers for the delivery of services for the home treatment of bleeding episodes associated with hemophilia, including the purchase of blood products and blood infusion equipment. (See N.J.S.A. 26:2S-10.1).

59. The Department of Banking and Insurance is authorized to designate the

hemophilia home care providers. Set forth below is a list of the designated hemophilia providers that have been designated by Department of Banking and Insurance in New Jersey.

D. Designated Hemophilia Home Care Providers

60. Currently, there are four major companies that are active providers. They are: (1) ADIMA d/b/a BioScrip, *(2) ACCREDO Health Group, Inc.*[9], (3) Coram, and (4) Bleeding Disorders Resource Network, LLC (BDRN).

61. There are other providers who are licensed but are not active in the market in a serious manner. They are:

- Caremark Rx, Inc.
- Children's Hospital Home Care
- New Life Homecare, Inc. ,
- Option Care Hemophilia Services
- . Med Pro Rx, Inc.
- . Walnut Home Therapeutics, Inc.

62. HANJ essentially has the power to "block" or veto the application of potential providers.[10] This is possible because of the role that they are given by the

[9] Accredo owns Pediatric Services of America, Inc. and Curative Critical Care Systems who are also designated providers

[10] See Department and Banking Website link http://www.state.nj.us/dobi/division_insurance/managedcare/omc/bulletin01_04.pdf

Department of Insurance and Banking regulations, which was published in Bulletin OMC 2001-04, states as follows:

> N.J.S.A. 26:2S-10.1. The list of acceptable providers would be composed of those health care providers that meet certain standards that ultimately must be set forth in regulation by DHSS. The minimum standards for the health care providers to meet are set forth in the statute (some aspects of the minimum standards may be subject to further interpretation), but the process for reviewing and accepting a provider's application to be on the list for purposes of contracting with carriers is not specified. Nevertheless, **DHSS has developed a preliminary list of acceptable providers after consulting with the Hemophilia Association**. The Hemophilia Association has significant expertise and experience regarding issues related to hemophilia and other bleeding disorders, and treatments thereof provided in different settings. **The Hemophilia Association has reviewed the practices and capabilities of those health care providers included on the list below, and the Hemophilia Association has indicated its belief that these providers meet the minimum standards as set forth under the Act.**

63. Accordingly, DHSS urges carriers to use the following health care providers in the provision of home care services and treatment of bleeding episodes related to hemophilia.

E. State-Federal Recognized Outpatient Regional Hemophilia Treatment Centers (HTC)

64. Carriers offering health benefits plans that are managed care plans must also provide payment to the clinical laboratory at a hospital with a State-recognized

outpatient regional hemophilia treatment center for covered services rendered to a covered person with hemophilia, regardless of whether the hospital's clinical laboratory is a participating provider.

65. The Department elected to specify the hospitals set forth below based upon their current federal designation as regional hemophilia treatment centers. As such they are all Federally Qualified Health Care Centers.

Children's Hospital of Philadelphia Specialty Center
New Jersey Section of Hematology/Oncology
1012 Laurel Oak Road, Building 1014
Voorhees, NJ 08043
HTC ID: 152; Region III

St. Michael's Medical Center
Nadeene Brunini Comprehensive Hemophilia Care Center
268 Martin Luther King, Jr. Blvd
Newark, NJ 07102
HTC ID: 055; Region II

UMDNJ - Robert Wood Johnson University Hospital
New Jersey Regional Hemophilia Program
Division of Hematology
One Robert Wood Johnson Place
P.O. Box 2601

New Brunswick, NJ 08903-0019
HTC ID: 054; Region II

Children's Hospital of New Jersey
Newark Beth Israel Medical Center
Valerie Fund Children's Center
201 Lyons Avenue at Osborne Terrace
Newark, NJ 07112

HTC ID: 070; Region II

The HTC's work very closely and have had routinely discuss funding, grants, patient referrals.

F. The Federal Role as a Payor for Blood Clotting Factor

66. There are approximately 646 hemophilia patients in New Jersey as of the end of the first quarter (Q1) of 2011. HHS had 401 of these active patients. As a result, Defendants have approximately sixty two (62%) of the New Jersey market share. As set forth below, Medicare and Medicaid are insurers of many of these patients. Attached hereto as exhibit Q[11] is a business record of Defendant Acreedo, accurate as of January 2011, that tracks patients[12] of Defendants who are beneficiaries of Medicare, a State Medicaid Agency or Tricare. In summary,

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[11] This document was provided by Plaintiff to the Government Prior to filing this suit, as part of his full and complete disclosure of all material information known to him to agents of the United States government and of the States. See ¶ 13

[12] The names of the patients have been redacted. An un-redacted version has been supplied to the Court and Defendant' counsel.

Defendants own records reflects the following number patients who are beneficiaries of a Federal Payor:

Medicare 149

New Jersey Medicaid..... 53

New York Medicaid..... 81

Virginia Medicaid..... 23

Ohio Medicaid.....16

Pennsylvania Medicaid..... 87

Connecticut Medicaid 10

Mass Medicaid 6

Maryland Medicaid..... 45

Maine Medicaid 39

Delaware Medicaid..... 3

District of Columbia..... 2

TOTAL MEDICAID..... 365

1. Medicare

67. The above numbers are generally consistent with studies conducted by or for the Government. According to the United States General Accounting Office (GAO), the Centers For Disease Control and Prevention (CDC) estimates[13] that approximately

[13] To determine this demographic information, the GAO used data from the 1993-1998 CDC Hemophilia Surveillance System Project, generally recognized as the most complete and accurate data

18,000 Americans, nearly all male, have hemophila and about 1,100, or 6% of these individuals are Medicare beneficiaries. *See Medicare Payment for Clotting Factor GAO-03-184*. This study also found that the Medicare sub-population and overall hemophila population do not differ in terms of the frequency of the disease type or severity of clotting factor deficiency.

68. Under Medicare Part B outpatient prescription drugs and biologicals are covered if they are not usually self administered and are provided pursuant to a physicians's services.

69. A federal analysis of 2010 Medicare spending found that Medicare paid an average of $217,000 annually per beneficiary for Factor for the 660 medicare beneficiaries nationwide with hemophilia A. *See Government Accountability Office. Medicare: High-Expenditure Part B Drugs*[14].

70. Based on the foregoing, it is plausible to conclude that of the 401 HHS patients, approximately 6%, or 24, are Medicare beneficiaries, at an estimated annual cost of $5,208,000.00[15] . This is a national average. The actual number, according the Exhibit Q, is 149 patients, but represents Medicare beneficiaries outside of New Jersey.

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available. *See Appendix I to GAO Report*

[14] Available at http://www.gao.gov/assets/650/649459.pdf

[15] The estimate is based on 24 patients at an average annual cost of $217,000.00 dollars

2. Medicaid

71. Approximately a third of people with hemophilia are covered through state Medicaid programs[16].

72. A 2008 CDC study of hemophilia and Medicaid found that the average cost of medications was almost $143,000 for each beneficiary per year.[17]

73. Based on the foregoing, it is plausible to conclude that of the 401 HHS patients in New Jersey, approximately up to one third, or 133 HHS patients, are Medicaid beneficiaries, at an estimated annual cost of $19,019,000.00 dollars.[18] This is a national average. The actual number, according the Exhibit Q, is 53 patients.

VII. UNLAWFUL CONDUCT

A. Medco's "Charitable Contributions"

74. Medco, through it's subsidiaries Accredo and HHS, makes, what it characterizes as "charitable contributions" to non-profit hemophilia support groups and foundations throughout the United States as a means of "inducing" or

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[16] Guh, S, Grosse SD, McAlister S, et al Health Care Expenditures for Medicaid Covered Males with Hemophilia in the United States 2008 Hemophila (2012), 18, 276-283 (2012) http://www.cdc.gov/ncbddd/hemophilia/documents/Guhmediacidhaemophilia2012_sy5.pdf

[17] Guh, S, Grosse SD, McAlister S, et al Health Care Expenditures for Medicaid Covered Males with Hemophilia in the United States 2008 Hemophila (2012), 18, 276-283 (2012) http://www.cdc.gov/ncbddd/hemophilia/documents/Guhmediacidhaemophilia2012_sy5.pdf

[18] The estimate is based on 133 patients at an average annual cost of $143,000.00 dollars

"influencing" the members of such hemophilia support groups, the substantial number of which are individuals with hemophilia, many of whom are also beneficiaries of a Federal Health Plan, to purchase their hemophilia factor drugs through Medco. As an example, see Exhibit C attached hereto which consists of a spreadsheet for Medco 2009 *"charitable contributions"* that is itemized by State, payee organization, stated purpose of the contribution, amount, and when it was delivered. The total budget amount for 2009 was $1,802,200.00 dollars.

75. In New Jersey, Medco, through Accredo and HHS, contributed $500,000 dollars or more to HSI through 2007, 2008 and 2009 annually. The intent was to funnel these funds to HANJ so that it could be used to support the hemophilia treatment centers and/or patients, all in order to "buy" influence and induce referrals to the Defendants. .

76. In New Jersey, the primary non-profit support group for hemophilia patients is HANJ. Attached hereto as Exhibits D-1, D-2 and D-3 are the IRS Form 990 Tax Returns for HANJ for the years 2007, 2008 and 2009. It identifies Hemophilia Services, Inc. (HSI) as a related organization through common membership, governing bodies, and trustees[19]. HANJ and HSI also share expenses for certain common employees.

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[19] See D-1, 2007 Form 990, Part VI, item 80a; D-2 2008 Form 990, Schedule R, Part II and D-3 2009 Form 990, Schedule R, Part II

77. In 2007, 2008 and 2009 HSI gave grants to HANJ each year in the amounts of $550,000, $525,000 and $500,000 respectively[20]. HSI's revenue for those same years are $697,506 in 2007 (listed as "Case Management[21]" revenues), $715,008 in 2008 and $629,758 in 2009.[22]

78. In 2007, HANJ received $550,000 in grant from HSI and provided $427,102 in "various grants and allocations"[23] and $675,304 in "assistance to specific individuals."[24] This represented 64 % of it's total receipts for that year of $1,730,792.[25]

79. In 2008, HANJ received $525,000 from HSI in gifts or grants[26] and then gave out grants and other assistance to individuals in the amount of $504,833.[27]

80. Likewise, in 2009, HANJ received $500,000 from HSI in gifts or grants[28] and then gave out grants to three hemophila treatment centers in the amounts of

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[20] See E-1, 2007 Form 990, Part II, Statement 1; E-2 2008 Form 990, Part II, Statement 1 and E-3 2009 Form 990, Schedule Part II, Statement 1.

[21] See E-1, 2007 Form 990, Part VII, line 93.

[22] See E-1, 2007 Form 990, Part I; E-2 2008 Form 990, Part I, and E-3 2009 Form 990, Schedule Part I.

[23] See D-1 2007 Form 990, Part II, line 22b and Statement 3

[24] See D-1 2007 Form 990, Part II, line 23 and Statement 4

[25] See D-1 2007 Form 990, Part I, line 1e

[26] See D-2 2008 Form 990, Part V, line 1c

[27] See D-2 2008 Form 990, Part IX, line 2

[28] See D-3 2009 Form 990, Part V, line 1c

$200,000 to Newark Beth Israel Medical Center, $50,000 to Saint Michael's Medical Center and $268,770 to Robert Wood Johnson Medical Center.[29]

B. Medco's "Charitable Contributions" Are Intended to Induce or Reward Referrals and are Measured By a Return on Investment (ROI)

81. Given that HHS contribution to HSI decreased from 550,000 in 2007 to $500,000 in 2008, HSI began, for the first time in 2008, to strenuously object and organized patients to reverse the cuts under threat that such patients would switch providers. Accredo also attempted to again reduce its funding to HSI in 2008, which at the time was approximately $500,000.00 dollars. The proposed reduction would amount to approximately $100,000.00 This was met with swift retaliation by HANJ using patients to threaten Accredo that they would obtain another provider for their "factor." An example of such letter[30] is attached as part of Exhibit Q and identified as Greenfield 0001. As a result of the potential losses, Accredo restored the funding

82. These communications resulted in discussion among HHS and Accredo sales representatives, including Relator, Karen B. Griffin (Vice President of sales for Accredo/HHS), Elena Bostick (Executive Director of HANJ/HSI, Board members of HSI, Craig Mears (Accredo President), as well members of the HHS sales team, Martha Occhiogrosso, Amy MacBeth (RN, HHS Account Manager), Danielle Kiesel and James Cline.

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[29] See D-3 2009 Form 990, Schedule I, Part II, line 1

[30] See Exhibit Q, marked as Greenfield 0001 -0080.

83. In 2009, Accredo acquired a smaller company known as Critical Care Services (CCS). CCS had a history of providing contributions to HSI equal to $5,000.00 per month. Upon its acquisition, Accredo honored the remaining part of this commitment which was due to expire in October 2009. HANJ was informed of this reduction in funding. Attached hereto is a series of emails that reflect the discussions and HSI's unhappiness over the reduction from Elena Bostick to Accredo officials between October 1, 2009 until November 15, 2009[31]. This funding continued through 2009 when Accredo again attempted to reduce funding. Elena Bostick now claimed that Craig Mears had "broken his word". Once again, this issue arose with respect to patients potentially using a different provider. The "funding" discussions that had ensued culminated in Accredo sending it's pledge to HSI for it's fiscal year ending June 30, 2010 (attached as Exhibit C[32]). The pledge partially restored the CCS funding.

84. In November 2009, Danielle Kiesel advised Craig Mears that Elena Bostick, HSI and HANJ were "*upset*" about "*cuts HHS was making to the HSI Contribution.*[33]" Accredo and HHS received reports that HANJ had contacted or spoke with patients who were members of HANJ to advise them of the HHS "*cuts*" and that patients, as a result, had switched their provider to one of their competitors, Bioscript.

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[31] See Exhibit P attached hereto. Marked as Greenfield 0778 to 0784

[32] Marked as Greenfield 0785 to 0786

[33] See Exhibit F-1, email dated November 13, 2009

85. As a result, Danielle Kiesel from Accredo contacted a HSI Board member about this issue. This began Accredo's inquiry into *"how many patients we have on our caseload that are receiving insurance through HSI.*[34]" Martha Occhiogrosso spoke with this particular patient and was told that he "*would not utilize a company that did not support HANJ and that he had already switched to Bioscript.*" It was in this context that Accredo began to discuss 2010 funding. Craig Mears assured his sales team that "*HHS will continue to be HSI's largest funding company of the program in 2010.*"[35] Upon hearing this news for 2010, Martha Occhiogrosso contacted the patient to confirm this with this patient.[36] Five days later, on November 18, 2009, Craig Mears (Accredo President) delivered to Elena Bostick (Executive Director of HSI/HANJ) the Accredo "Pledge Letter" for 2010.[37]

86. The discussions between Accredo/HHS and HANJ/HSI continued through the early part of 2010. This became a great concern to Accredo and the possible impact on it's business. Amy Macbeth reported to Relator that HANJ and HSI advised Accredo staff in an "*hour long*" conversation that (i) it is likely the New Jersey HTC's will join the NY consortium and (ii) a manufacturer was going to offer the NY

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[34] See Exhibit F-2, emails from Craig Mears (President) and Danielle Kiesel dated November 13, 2009

[35] See Exhibit F-3, emails from Craig Mears (President) and Amy Macbeth dated November 13, 2009

[36] See Exhibit F-4, emails from Craig Mears (President) and Amy Macbeth dated November 13, 2009

[37] See Exhibit F-5, email and letter from Craig Mears (President) to Elena Bostick dated November 18, 2009

consortium additional discounts in addition to the already low 340B pricing[38], which would put Accredo at "*an even greater disadvantage in the pricing.* The "funding" continued to be "negotiated" and the issues escalated in the Summer/Fall of 2010. Attached hereto as Exhibit D[39] is a series of emails that reflect the tension that exists with respect to the funding requests and HANJ's continued threats to join the New York 340B Consortium or have the HTC's apply for 340B status.

The tension and what is "at stake" over the "funding" is appropriately captured in the Q4 2010 Business Plan provided by Amy MacBeth, Account Manager, a copy of which is attached hereto as Exhibit E[40] . Some of the pertinent parts are as follows:

> . . . . 2010 YTD - 79% of the new factor business is derived from Hemophilia Treatment Centers, and 21% is None - HTC driven. ***HHS reduction in program funding may have a significant impact on NJ HTC referring practices in Q4. Based on market intelligence, HTC's have been notified of this funding reduction and at least one HTC has begun to accelerate discussions regarding the benefits of utilizing competitive HSI providers with new patients . . . .***

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[38] The 340B Drug Pricing Program resulted from enactment of Public Law 102-585, the Veterans Health Care Act of 1992, which is codified as Section 340B of the Public Health Service Act. The 340B Drug Pricing Program is managed by the Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs (OPA). Section 340B limits the cost of covered outpatient drugs to certain federal grantees, federally-qualified health center look-alikes and qualified hospitals. Participation in the Program results in significant savings estimated to be 20% to 50% on the cost of pharmaceuticals for safety-net providers. The purpose of the 340B Program is to enable these entities to stretch scarce federal resources, reaching more eligible patients and providing more comprehensive services. Medicaid reimbursement is generally based on a drug's average wholesale price (AWP), which usually exceeds the actual cost paid by the HTCs.

[39] Marked as Greenfield 0787 to 0798

[40] Marked as Greenfield 0799 to 0805

area."

87. Macbeth suggested offering Bostick a role as a "*consultant or an educational role with HHS" which may allow the Company to "support the requested donation.*[41]" Relator reported this to Karen Griffin (Accredo/HHS vice president of sales). In addition he advised Griffin that HSI advised that they now "*provides insurance to 59 of our (Accredo) patients at an average cost between 12 and 20 thousand dollars per year (far exceeding our contribution).*"[42] It was emphasized that the HANJ/HSI Board would be meeting soon to discuss whether to move for 340B status.

88. The funding concerns were discussed further on July 14, 2010 at a meeting between Accredo (Relator and Amy Macbeth) with HANJ (Bostick, Rita Matagrano (HSI Program Coordinator) and Genevieve Christo. The discussion revolved around the fact that HANJ *"has 77 insurance recipients, of which 59 are HHS clients."*[43] Despite this effort and demands, Medco, based on concerns related to "compliance issues," made it clear there might be no "*additional*" funding,[44] and used the pretext of budgetary constraints. The "compliance issues" related to the long existing correlation between funding and referrals.

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[41] See Exhibit G-1, email from Amy MacBeth to Relator dated July 15, 2010

[42] See Exhibit G-2, email from Relator to Karen Griffin dated November 13, 2009. This information was provided to Relator from HANJ

[43] See Exhibit G-3 minutes of Accredo/HANJ meeting of July 14, 2010

[44] See Exhibit G-4, email from Relator to Karen Griffin dated July 28, 2010

89. Moreover, according to Karen Griffin, Accredo's vice president of sales, as 2010 drew to a close, it became clear that because Accredo's charitable funding from Medco had been or was going to be cut in half, then HANJ's funding was also going to be cut in 2011.[45]

90. During a meeting on October 12, 2010 Elena Bostick, Executive Director of HANJ described a quid pro quo arrangement made years previously, with Craig Mears. According to Bostick, this arrangement provided money to fund insurance for patients, specific to the company, allowing factor product to be provided. This evolved into a mechanism to "effectively block competition, as HANJ would control admittance of new companies able to provide hemophilia factor." HANJ would fund local referring sources, ensuring that they would not become competitive entities and would drive referrals, based on funding receipt. Elena Bostick again outlined the number of HHS patients HANJ maintained along with the amount of money she insisted was required for each patient, and in toto.

91. Bostick requested a second meeting with Accredo's Mid-Atlantic team on November 3 2010. She again reiterated the original agreement, the number of patients that HHS should fund and the consequences if funding was not received.

92. When told the money might not be doubled to $400,000 Elena said additional competitors would now be authorized adding *"you do what you have to do and we'll do what we have to do".* Medco understood these ramifications and

[45] See Exhibit H, email from Karen Griffin to Relator dated November 2010

gathered business intelligence to determine the possible impact in amounts needed to avoid this business loss. Reduction in payments to the HTC referral sources would force a reduction and possible elimination of all referrals.

93. While Medco was determining the business case for additional funding Elena contacted her board and began a campaign to convince patients to switch their service. HANJ's actions immediately created losses at Medco while sending the message that previous funding must be restored.

94. Patients were contacted along with referring facilities and losses increased. A new competitor was added and publicized with HANJ recommending this as a new alternative. HANJ sent letters to their membership asking that they personally call a competitor and thank them for their contributions while simultaneously sending a letter deriding Medco for its inadequate funding.

95. In response to this "*cut in funding*" HSI organized a letter writing campaign by its members to pressure Accredo and HHS and personally advised referral sources at the HTC's as well as Board members. By letter dated March 18, 2011 from Jerry Seltzer, HSI president, he stated to HSI members that, *"because HHS/Accredo has chosen to reduce its financial support so significantly, that as a major participant, this reduction places the HSI insurance program in jeopardy of being phased out, and ceasing to exist in the foreseeable future."* Further, Seltzer urged the members *"if you are a client of HHS/Accredo . . . . on behalf of the HSI Board. . . . contact Craig Mears, President of HHS.* In closing, Seltzer stated that *"if*

we don't receive a commitment from HHS/Accredo in restore financial support for the coming year (2011), sadly, we will have to notify the State of NJ that the very successful Insurance program. . . . is in danger of being phased out due to lack of funds." [See Exhibit I-1, HSI letter dated March 18, 2011].

96. Letters addressed to Craig Mears of Accredo/HHS from clients and HSI members soon arrived. As an example of the many that were sent, see Exhibit I-2, letter from Gary E. Squire dated March 21, 2011 and Exhibit I-3 from Donald Goldman dated March 19, 2011. These are examples of significant number of letters that were received. In total, approximately 75 letters were received from patients between March 2011 and May 2011. Copies of these letters [with patient names redacted] are attached hereto as Exhibit 0 and marked as Greenfield 002 to 080. These patients were then instructed to report back to Elena Bostick with a summary of how Accredo was responding or intending to respond.

97. In response to this pressure, Accredo/HHS began to analyze the potential impact and loss of business that they were experiencing and could experience in the future. Customer representatives Danielle Kiesel, Martha Occhiogrosso and Jim Cline put together a list of HHS clients and members of HSI at the request of the President Mears. See Exhibit J and K for copies of emails and a list which showed that a total of 37 HHS clients who were also members of HSI. Quite alarmingly, nine (9) people on the list where either Board Members or immediate family members of Board members.

98. Craig Mears, President of Accredo, then decided on April 28, 2011 to have an analysis performed on "HSI NJ Business Return On Investment (ROI)" and assigned this task to Relator and Adam Bryan, asking that they address the following questions:

1. *Is there quantifiable ROI we can point to if we move from $175K to 350K?*
2. *What is likely business deterioration to NJ market share if we don't increase?*
3. *What is size of overall fund and what % does Medco contribute?*
4. *What % of market share do we currently have?*
5. *What is the YOY trend?*

99. The following day, they provided the following responses:

Is there quantifiable R0I we can point to if we move from $175k to $350K?

Prevent potential loss of 51,538,880 units currently dispensed to patients utilizing NJ HTC's. This number seems high if the only risk is for patients utilizing NJ HTCs. I show that for the last 12 months, patients that have NJ HTC's have utilized approximately 43 million units with gross margin of $9,2 million. If all NJ patients are considered at Risk, this number is significantly higher (see below). We have seen since 2008 a 10% increase in units (4MM) per year. The ROI would include a stabilization of this number.

What is likely business deterioration to NJ market share if we don't increase

NJ HTC's will resort to developing 340B programs placing all new and existing business at risk. For any patient that switches to a 340B program, we will lose 100% of the margin associated with that patient unless we are able to service the 340B program, in which case we will lose approximately 50% to 60% of the margin depending on the contracted 340B rates and assuming consistent usage.

Currently 57 plus (new patients added in 2011) HHS patients utilize the Hsi insurance program. Of those patients, most are very high volume prophy patients who are at risk of losing insurance or moving to another provider. The NJ HTC patients all seem to be big users.

New and existing business erosion with the addition of to two new HSI providers (BDRN and Coram) in 2011.

What is size of overall fund and what % does Medco contribute?

Per our discussion - HSI receives approximately 2 million dollars per year to fund their program . Medco percentage based on previous and current contributions would be about 17%.

What % of NJ market share do we currently have?

HHS services the majority of the patients in the NJ market with the exception of the Aetna and Cigna lives. State of NJ approved HSI providers include Bioscripts, HHS, Bleeding Disorders Resource Network and Coram. Bioscripts has approx 40 patients primarily because they are the Aetna provider in NJ. BDRN has a handful. We have at least 95% of Horizon BCBS NJ patients. Horizon is the largest Payer in the state with 3 million lives. HHS is one of two providers for HNJ Health 450,000 lives which is the managed Medicaid arm of Horizon BCBS NJ. As of the end of 012011, HHS has 401 active patients with a patient state of NJ. The estimated total Hemophilia population for the state of NJ based on 2010 census data is 646 patients. Assuming one hemophilia patient per 13,600 residents, then HHS has a total market share of 62% (401/646).

What is overall profitability of NJ Hemophilia market?

Per December 2010 dashboard:

Net Revenue $59,034,165.10

Total GM $10,181,227.58

Total GM% 17.25%

Based on the last 12 months with a patient state of NJ:Net Revenue $77,114,302.29

Total GM: $15,649,757.08

Total GM% 20.29%

What is the YOY trend?

YOY Trend - Units dispensed through NJ HTCs only:

2009 Q1 Units: 6,826,787

2009 Year End Total Units: 34,596,192; 2010 Q1 Units: 9,557,159

2010 Year End Totals: 40,295,973

2011 Q1 Units: 11,242,907

100. Based on this analysis, Accredo convinced Medco to restore funding to $350,000 and commit for FY 2012. This was confirmed in emails between Craig Mears and Bruce Scott dates May 11, 2011, May 19, 2011 and December 9, 2011 [see Exhibits L-1, L-2 and L-3].

101. This was discussed at length at a meeting held on December 19, 2011 with Bruce Scott (now Vice- President), Diana Florio[46], Vice President, Kirk Cothum, Vice President, Craig Mears, Accredo President and Relator. Attached hereto as Exhibit L-4 is Relator's contemporaneous notes of that meeting. HSI made it clear to Accredo that they provide insurance for 72 patients of 58 are Accredo patients. Set for below are highlights from that meeting that:

[46] In October of 2011 reorganization at Accredo created new lines of authority, with Craig now moved to a Vice President of marketing role and the committed money for HANJ in question. The new VP of sales Diana Florio realized that sales were suffering as a direct result of this funding issue and brought it to the attention of Bruce Scott Pres. of Accredo's infusion business unit. Bruce then called a meeting on December 11, 2011 with Accredo's vice presidents, asked if a business analysis had been completed and said that the decision to fund would be based on the return on investment

Craig: Let me Start with a summary on what has happened so far. ***Last year our contribution was cut in half from 500,000 to HSI. We communicated the change and they told their patients. We then saw a decline in business. At that point I worked with Bruce to see about increasing their funding. We committed to increase their funding by another $175,000 starting in January to $350,000. They were more approaching this from a business standpoint.*** *They said they had 72 patients and 58 patients were Accredo's. They said they wanted more to fund our patients.* Over the years Gentiva was acquired by Accredo as was HRS PSA and CCS. They all provided funding, which has decreased. They think the funding should stay the same and are mad that we aren't paying.

Bruce: How has this affected our business? *Have our margins decreased and if we increase back up to 350 will they stop throwing us under the bus*?

Kirk: Also what Is the profile of the patient?

Craig: HANJ provides insurance for patients similar to PSI for Virginia only PSI does a yearly review .

Bruce: How does this compare to others?

Craig: PSI at a Virginia has a two-year max and HPPS out of Philadelphia. They get a lot of manufacturer funding and use that to the support the HIC's.

Amy: *They're very upset with us... they see the funding being cut and want an amount that will pay for our patients. Bio scrip stepped up and provided some funding.*

Bruce: Do we know the size of contributions from Other Donors?

Amy: No

Craig: We have some intelligence on that I'll have to see if I can find. They have $4 million in the bank and use that to support their HTC's. Unfortunately they look at this based on

a business transaction because of our 58 patients and they want an equivalent amount to be paid. I spoke with Elena about increasing costs.

Diana: Is Mark Scuderi Involved?

Craig: Last year he was very much involved and he relayed much of this information to Elena and the board. Carl Piercey has taken over the board. He has more dislike for us than probably anyone. I sent in the budget and Rich said we're not increasing but reducing by 200,000.

Bruce: What's in the plan?

Craig: $175,000. It was supposed to be another 175,000 but somehow wasn't submitted. I think we need to circle back with the Medco foundation. Can we pull from the Boys Club of America?

Bruce: ***How bad are we being hit***?

Amy: We've lost over 1 Million Units during the last year.

Bruce: Is Amy Johnson running profitability on that?

Craig: Margin is decreasing. I had Amy Johnson pull the numbers... we were down 1.6 million in profit margin year-over-year. We also gave NJ health some concessions.

Bruce: So this is a business decision?

Craig: Yes, you Frank and I were going in to speak with them. As far as going back in, the question is whether they will accept that or continue to badmouth us and do everything to steer business to another provider. I think we need to get an answer. I hate to be blackmailed.., it doesn't feel right.

Diana: *Can we pay monthly? If we pay them in monthly amounts we can make sure they're not cutting our business. If they don't stop badmouthing us we can just cut them off.*

Kirk: *So If We Don't Do This they would continue to decrease our business?*

Amy: *They communicate with the HTC's and fund the HTC's so our business will decrease*

Bruce: *Well if they are bad mouthing us we won't fund them.*

Kirk: *I like Diana's idea of quarterly or monthly payments so that we can be sure our business doesn't decline.*

Craig: What shall we do for next steps?

Bruce: I want to see financials. Kirk could you look at the budget?

Kirk: HHS has about 550,000 in total. The HSI line is 175,000.

Craig: We will also need to determine with Rich's Cut of 200,000.

Bruce: *The answer must be driven to the business case, we must be careful.*

Craig: I'll follow-up with Charles Johnson regarding the 2012 budget. Bruce: Okay you'll get the info out when do we need to get back?

Amy: Yes, they tell the community to switch

Diana: We should set up another meeting for this group

Bruce: *So we are looking to restore to 350 and have a conversation.*

Craig: *I agree but I don't know if they will agree.*

Amy: So for now we just hold off contacting them?

Craig: I'll get the information out to everybody and we'll set up another meeting

102. Soon thereafter, Craig Mears received authorization from Medco, after the issue and explained to them and informed that they will *"find the additional money."* Mears reported this to the others at a meeting January 6, 2012. A transcribed copy the conversations from that meeting are attached hereto as Exhibit L-5. To drive home the point that these funds were in exchange for patient referrals, Bruce Scott stated:

> . . . okay, so we're at the point where they understand that we are willing to continue and willing to increase our contribution back to 350K and it is clear to them that we are not wiling to contribute to an organization that is placing us in an unfavorable position with patients . . .

103. There is no doubt that the management of Defendant's knew that their actions were illegal. Set forth below is a transcript of Region Meeting that took place on January 24, 2012[47] were this illegal kickback scheme was openly discussed.

Region meeting: January 24, 2010

Attendees:

Diana Florio, Vice president sales,

Steve Greenfield, Area VP

Amy McBeth, Account manager,

James Cline, Customer Account Manager

Evelyn Tezak, Customer Account Manager

Martha Occhiogrosso, Customer Relations Specialist

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[47] A hard copy of Relator's transcription of the Meeting is attached hereto and marked as Exhibit L-6.

Michelle Porter, Customer Relations Specialist

Augusta Reichwein, Customer Relations Specialist

Melissa Kendrick, Customer Relations Specialist

Beth Patrick, Customer Relations Specialist

David Dwyer, Customer Relations Specialist

Amarilis Peralta, Customer Relations Specialist

Elcie Estinvil, Customer Relations Specialist

Christine Hayes, Customer Account Manager

Michelle: The only thing that concerns me is that these people are very educated very savvy they notice if we are not sponsoring something..... We hear about it... We heard about it with HANJ and my goodness the letters...

Evelyn: Well, maybe with the change in helm we can cut back... With Elena leaving and stuff.

Jim: Elena is not leaving... Maybe in a year ...Ann Rogers is leaving maybe we can cut back there.

Martha: We can cut them (HANJ) ...but then we lose patients and they write those nasty letters...

Diana: *This year we'll give a lump sum and then pay quarterly but if they start bad mouthing we'll cut them off... So either play nice in the sandbox... Or we take the money away.*

Jim: Yeah just don't bad mouth us and were cool

C. Medco's "Charitable Contributions" Are Illegal Renumeration under The Anti-Kickback Act

104. A review of the facts and evidence presented herein against the standards laid out in the HHS-OIG Advisory Opinion shows the clear failure to meet the standards and expectations to avoid a violation of the AKS. Set forth below is a

comparison of the standards and the practices of Medco.

105. ***No Donor Control, (direct or Indirect) over Charity***. *First, no donor or affiliate of any donor would exert direct or indirect control over the Foundation or its programs. The Foundation would be an independent, nonprofit, tax-exempt charitable organization that would have absolute, independent, and autonomous discretion as to the use of donor contributions. Donors or affiliated individuals would not serve on the Board in a voting or non-voting capacity, nor would donors or affiliated individuals serve on panels that make recommendations on grant applications.*

Contrary to the above, Defendants exercise control by providing substantial funding and in return requires positive references, referrals, preferential treatment and publicity. Contributions are based on attainment of the above and Defendants business ROI.

106. ***Independent Grant Awards By Charity***. *Second, the Foundation would award financial grants in a truly independent manner that severs any connection between donors and recipients of grants.*

Contrary to the above, the prohibited connection between donor and recipient is violated repeatedly with regular communication to recipients regarding reduction in funding and correlating these as a direct threat to the recipients circumstance. HTC recipients are referral sources who were given direct information regarding donor funding. Patient recipients also receive direct communication and were asked to contact donor and/or switch to a competitor.

Moreover, the "contribution" represents 17% of grant funding, whereas the Requestor identified in the HHS-OIG Advisory Opinion represented that it would not exceed 10% (representing an increase of 50%).

107. ***Awards Made Without Regard To Donor's Financial Interest***. *Third, the Foundation would make financial grants without regard to any donor's financial interest and without regard to whether the recipient refers patients for a donor's products, services, or supplies. Donors would not be permitted to impose any*

restrictions on use of their contributions, except that donors could earmark contributions to be used for a specific coagulation disorder. Donors would not be told the specific use to which their donations were put, nor would recipients of grants be told the identity of the particular donor that contributed to an award.

Contrary to the above, the foundation [HANJ] repeatedly references donor revenue growth, positive financial impact by grant programs and proportional amount of business gained. Foundation provides grants and direct information to recipients regarding donor financial, "contribution" and with correlation to the number of donor customers. Awards are made, proportional to the size of the recipient program and number of patients maintained. Referring entities provide patient referrals in proportionate amount to donor investment. This is demonstrated by a direct correlation to the number of referrals received and the amount of funding provided. For example, the largest donor will receive the largest number of referrals. Conversely, and according to Accredo documents, as donor funding decreases so also do referrals and business.

108. ***No Connection To referrals.*** *Fourth, neither the Foundation nor any of the Requestors would provide donors with any information that would enable a donor to correlate the amount or frequency of its donations with the amount or frequency of referrals or use of its products, services, or supplies.*

Contrary to the above, the foundation freely discusses and provides documentation, directly indicating the amount or frequency of donations matched to the number of donor patients receiving awards. Again, as funding for foundation was decreased, the Company saw an immediate and sustained decline in business. As funding was increased, referrals and business growth resumed.

109. ***No referrals By Charity.*** *Sixth, the Foundation itself would not make any referrals to physicians or other service providers and would not provide any*

recommendations with regard to any particular drug, supply, or DME item used to treat coagulation disorders. The governing documents of the Foundation would prohibit Board members, officers, and other staff from making any referrals to physicians, suppliers or other health care providers and would not provide any recommendations with regard to any particular drug, supply, or item of DME used to treat coagulation disorders. Moreover, the Member Organizations, which have representatives on the Board in a non-voting capacity and may also apply for grant funds, do not provide health care services or bill Federal health care programs.

Contrary to the above, referrals are made by both HTC entity and foundation contrary to OIG guidelines. With funding decrease in 2011, referrals decreased and were eliminated by the foundation. By 2012, and notification of donor funding restoration, referrals resumed one week later.

110. A comparison of the OIG standards with the practices of Defendants herein demonstrates that the Defendants have violated AKS.

D. Medco's Contributions Induce The Bulk of Referrals From the HTC's

111. The HTC's work very closely and routinely discuss funding, grants, patient referrals. As a result of Medco's funding to HSI and HANJ, they have achieved dominance in the market. As an example, Baxter, which is one of the largest manufacturers of "factor," sells more factor to Accredo by a huge margin than any other provider.

112. Accredo also purchases factor from many of the other largest manufacturer. Set forth as Exhibit M is a summary of all factor sales by Baxter that includes patients from the HTC's from 2007 through 2009. The numbers show Accredo's dominance as follows:

PROVIDER	2009 Sales	Percentage of Market (rounded)
Accredo	8,393,233	83%

Caremark	713,450	8%
Genesis	234,468	3%
Bioscrip	136,555	2%
Anthem	166,443	2%
Cigna	43,600	0.5%
BDRN	82,810	1%
CORAM	24,120	0.5%
TOTAL	10,187,079	100%

113. As the events that are described herein unfolded, HANJ kept the care coordinators, such as Ellen White at Newark Beth Israel, updated. The HTC's are informed what contributions Medco makes and is aware that , at least in part is a source the funds that HANJ uses as grants to the HTCs.

E. Defendant's Practice of Providing Meals, Gifts and Equipment to Induce Hemophilia Patients to Purchase "Factor" is Illegal Renumeration Under the Anti-Kickback Act

114. Attached hereto as Exhibit N is a summary schedule of some expense reports submitted by Medco sales representatives which itemizes the date, amount, patient, insurer, amount of "factor" supplied to the patient and a description of the type of expense. In each case, the dinners, lunches, gifts, refrigerators, equipment and all exceed the safe harbor[48] amount of ten dollars ($10.00) per item and a fifty dollar ($50.00) annual limit. It is important to note that this schedule represents examples of a rampant practice which is repeated thousands of times throughout the country.

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[48] The OIG has interpreted the prohibition to permit Medicare or Medicaid providers to offer beneficiaries inexpensive gifts for enforcement purposes are those that have a retail value of no more than $10 individually, and no more than $50 in the aggregate annually per patient.

115. The individuals identified on Exhibit N became active patients[49] of HHS as a result of "referrals" from the HTC's that are part of the "contributions for referrals" scheme alleged in this Complaint. A review of Exhibit N shows that these HHS patients were insured by many of the State Medicaid programs (e.g. PA, NY, NJ, Connecticut, VA, Maryland), and Medicare among other federal insurers.

116. As a Pharmacy Provider who has and maintains billing privileges with Medicare, Accredo entered into a Provider Agreement CMS Form 855s. This Provider Agreement states as follows:

> **Section 15 CERTIFICATION**
>
> . . .
>
> 3. I agree to abide by the Medicare laws, regulations and program instructions that apply to this supplier. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. **I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law)**, and on the supplier's compliance with all applicable conditions of participation in Medicare.

117. Medco sales representatives provide and give to patients who they supply with "factor" gifts, which include dinners, lunches, gifts, refrigerators, and equipment, all of which exceed the safe harbor amount of ten dollars ($10.00) per item and a fifty dollar ($50.00) annual limit. Exhibit N is a summary schedule of some

[49] The names of the patients have been redacted to protect their privacy. An "unredacted" copy has been supplied to the Court and Defendants.

expense reports submitted by Medco sales representatives which itemizes the date, amount, patient, insurer, amount of "factor" supplied to the patient and a description of the type of expense.

118. This represents an intentional plan to induce the patient's continued use and selection of Accredo as their provider. This practice is a common and regular occurrence with Medco's specialty pharmaceutical patients, including hemophilia patients throughout every region of the Country with the knowledge of Craig Mears, President and Diana Florio, vice president, and totals hundreds of thousands of dollars each year.

119. Gifts to pharmacy patients is a kickback that constitutes a violation of a certification of compliance to a Federal Health Care program. Compliance with federal and state statutes prohibiting kickbacks is a material condition to payment under Federal and state government healthcare programs provides the essential link between the AKA violation and the FCA claim.

120. This represents an intentional *plan to induce the patient's continued use and selection of Accredo as their provider.* This practice is a common and regular occurrence with Medco's specialty pharmaceutical patients, including hemophilia patients throughout every region of the Country with the knowledge of Craig Mears, President and Diana Florio, vice president, and totals hundreds of thousands of dollars each year. The hemophilia patient population is limited, but the care for this condition is extraordinarily expensive. As set forth in paragraphs 66 though 73, a substantial portion of this cost is borne by Federal Health Care programs. The market

place for providers is competitive but also limited. The practices of Medco described herein corrupts this market by restricting competition and results in excess cost to the federal fisc.

F. Violations of The Anti-Kickback Act ("AKA")

121. The Federal Courts have determined that compliance with the Anti–Kickback Statute is a precondition of payment. This conclusion is "rendered inescapable when the purpose of the Anti–Kickback Statute is considered within the context of the Medicare statute." *42 U.S.C. § 1395y(a)(1)(A)*. Moreover, courts, without exception, agree that compliance with the Anti–Kickback Statute is a precondition of Medicare payment, such that liability under the False Claims Act can be predicated on a violation of the Anti–Kickback Statute[50].

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[50] *See, e.g., Willis v United Health Group,* 2011 WL 2573380 (2011), ("Compliance with the [Anti–Kickback Statute] is clearly a condition of payment under Parts C and D of Medicare); *United States ex rel. Kosenske v. Carlisle HMA, Inc.,* 554 F.3d 88, 94 (3d Cir.2009) ("Falsely certifying compliance with the ... Anti–Kickback Act[ ] in connection with a claim submitted to a federally funded insurance program is actionable under the [False Claims Act]."); *United States ex rel. Schmidt v. Zimmer, Inc.,* 386 F.3d 235, 243 (3d Cir.2004) ("A certificate of compliance with federal health care law is a prerequisite to eligibility under the Medicare program.") *Pogue,* 565 F.Supp.2d at 159 ("Legion other cases have held violations of [the Anti–Kickback Statute] ... can be pursued under the [False Claims Act], since they would influence the Government's decision of whether to reimburse Medicare claims."); *Rogan,* 517 F.3d at 452 (rejecting the argument that a kickback was immaterial to the validity of Medicare and Medicaid claims); *McNutt ex rel. U.S. v. Haleyville Med. Supplies, Inc.,* 423 F.3d 1256, 1259 (11th Cir.2005) ("[C]ompliance with federal health care laws, including the [Anti–Kickback] Statute, is a condition of payment by the Medicare program.");; *United States ex rel. Ortega v. Columbia Healthcare, Inc.,* 240 F.Supp.2d 8, 13 n. 5 (D.D.C.2003) (holding that "[c]ompliance with [the Anti–Kickback Statute] is a condition for reimbursement under Medicare"); *United States v. Ruttenberg,* 625 F.2d 173, 177 n. 9 (7th Cir.1980) (stating that Congress need not "have spelled out duties, beyond the duty of avoiding receipt and payment of kickbacks"); *United States ex rel. Lisitza v. Johnson & Johnson,* 765 F.Supp.2d 112, 127 (D.Mass.2011) (Stearns, J.) ("The court agrees that in the case of the [Anti–Kickback Statute], compliance is not merely a condition of participation in federal health care programs, but is also material to the government's decision to pay any claim resulting from a kickback."); *United States ex rel. Fry v. The Health Alliance of Greater Cincinnati,* No. 1:03–CV–00167, 2008 WL 5282139, at *12 (S.D.Ohio Dec.18, 2008) ("The claims at issue in this case ... involve certification of compliance with the Anti–Kickback Statute, a condition of government payment."); *United States ex rel. Thomas v. Bailey,* No. 4:06CV00465 JLH, 2008 WL 4853630, at *8 (E.D.Ark. Nov.6, 2008) ("[C]ase law supports the proposition that compliance with the Anti–Kickback Statute is a condition of payment under [the federal health care programs, including Medicare]."); *In re Pharmaceutical Indus. Average Wholesale Price Litig.,* 491 F.Supp.2d 12, 18

122. The Medicare program requires providers to affirmatively certify that they have complied with the Anti–Kickback Statute. Failure to comply with the kickback laws, therefore, is, in and of itself, a false statement to the government."); *United States ex rel. Smith v. Yale Univ.*, 415 F. Supp.2d 58, 91 (D. Conn.2006). Medicare Regulations and the CMS Provider Agreement expressly provide that certification is a precondition to governmental reimbursement. In order to obtain reimbursement and as a condition to governmental payment, providers must certify that they are in compliance with the terms on the Provider Agreement; *Bidani,* 264 F.Supp.2d at 615–16 (finding a violation of the Anti–Kickback Statute "material to the government's treatment of claims for reimbursement" and that to find otherwise, "would put the government in the position of funding illegal kickbacks after the fact"); *United States ex rel. Kneepkins v. Gambro Healthcare, Inc.,* 115 F.Supp.2d 35, 43 (D.Mass.2000) (O'Toole, J.) (holding that alleged violations of the Anti–Kickback Statute were sufficient to state a claim under the False Claims Act, despite no express certification of compliance with applicable law); *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.,* 20 F.Supp.2d 1017, 1047 (S.D.Tex.1998) ("[E]xplicit certifications of compliance with relevant healthcare laws and regulations ... provided evidence that the government conditioned its approval, payment and Defendants' retention of payment funds on those certifications.").

123. Defendants herein have and maintain billing privileges with Medicare,

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(D.Mass.2007) (Saris, J.)

and have entered into a Provider Agreement CMS Form 855s. This Provider Agreement contains a certification that each provider must certify as follows: "*. . . I agree to abide by the Medicare laws, regulations and program instructions that apply to this supplier. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare.*"

124. The practices and activities described herein are violations of the False Claims Act in that the Defendant's actions violate the Anti-Kickback Statute and such transactions do not fall within any safe harbor provision. They, in turn, have therefore falsely certified and have caused their customers to also falsely certify that they are in compliance with the Anti-Kickback Statute.

VIII. CAUSE OF ACTIONS

125. With respect to each of the causes of action set forth herein, it is understood that all of the allegations set forth herein in paragraphs 1 - 124 are incorporated into each of these counts as if they were fully set forth therein.

A. COUNT ONE

THE FCA: 31 U.S.C. § 3729(a)(1)

126. The Defendants knowingly caused to be presented and /or presented false or fraudulent claims to Federal Health Care Programs and knowingly made, used

or caused to be made or used, false statements to get said claims paid by Federal Health Care Programs as follows. The Federal FCA, 31 U.S.C. § 3729(a)(1)[51] makes "knowingly" presenting or causing to be presented to the United States any false or fraudulent claim for payment, a violation of federal law for which the United States may recover three times the amount of the damages the government sustains and a civil monetary penalty of between $5,500 and $11,000. Defendant's actions as described herein, including but not limited to the contributions and payments to charities and other entities as well as excessive gifts to patients were illegal inducements, and were taken to present a false claim for payment.

B. COUNT TWO

THE FCA: 31 U.S.C. § 3729(a)(2)

127. The Federal FCA, 31 U.S.C. § 3729(a)(2) makes "knowingly" making, using, or causing to be used or made, a false record or statement to get a false or fraudulent claim paid or approved by the Government, a violation of federal law for which the United States may recover three times the amount of the damages the Government sustains and a civil monetary penalty of $5,500 and $11,000. Defendant's actions as described herein, including but not limited to the contributions and payments to charities and other entities, as well as the excessive gifts to patients are illegal inducements, which caused Defendants to make a false statement or record to get a

[51] On May 22, 2009, the Fraud Enforcement and Recovery Act (FERA) was enacted into law which, inter alia, amended the False Claims Act. Part of the amendment renumbered ceratin sections. Under FERA, effective 5/22/09 3729(a)(1) became 3729(A)(1). Likewise, 3729(a)(2) became 3729(A)(2) and 3729(a)(3) became 3729(A)(3) . Since the allegations include a time period before and after 5/22/09, references are to be applicable sections

false claim paid.

C. COUNT THREE

THE FCA: 31 U.S.C. § 3729(a)(3)

128. The Federal FCA, 31 U.S.C. sec. 3729(a)(3)[52] makes any person, who conspires to defraud the United States by getting a false or fraudulent claim allowed or paid, liable for three times the amount of the damages the Government sustains and a civil monetary penalty of between $5,500 and $11,000.

129. Defendants Medco, Acreedo and HHS agreed on the plan to use charitable contributions and gifts to induce the referrals described herein and each shared in the general conspiratorial objective and each committed overt acts described herein in ¶ 74 through ¶ 118 in furtherance of the conspiracy. These overt acts by Medco, included, inter alia, providing the funding for the charitable contributions,[53] performing a material role in the decisions to restore and increase the contributions,[54] and paying for the excessive gifts to existing patients.[55]

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[52] Section 3729(a)(3), now section 3729(a)(1)(C), was amended to correct the Supreme Court's erroneous holding in *United States ex rel Sanders v Allison Engine Co.*, 553 U.S. 662 (2008). Congress wanted to *"specifically address the intent requirement read into the section by the Court . . . As a result, the provision now just extends FCA liability to those who conspire to commit a violation any of substantive section of 3729(a)"* See S. Rep. No. 111-10, at 12 (2009). The amended language removed the words *"defraud the Government by getting a false or fraudulent claim allowed or paid"* and now applies to any person who *"conspires to commit a violation of subparagraph (A), (B), (D), (E), (F) or (G)."*

[53] See ¶¶ 74, 75, 111, 113 and Exhibit C

[54] See ¶¶ 92, 93, 100

[55] See ¶¶ 114, 115, 117, 118, and Exhibit N

D. COUNT FOUR

Violations of the California FCA by Defendants

130. Defendants violated the California FCA in the following respects:

a. California Government Code §12651(a)(1) prohibits a person from knowingly presenting or causing to be presented to an officer or employee of the state or of any political subdivision thereof, a false claim for payment or approval.

b. California Government Code §12651(a)(2) prohibits a person from knowingly making, using, or causing to be made or used a false record or statement to get a false claim paid or approved by the state;

c. California Government Code §12651(a)(3) prohibits a person from conspiring to defraud the state by getting a false claim allowed or paid by the state; and

d. California Government Code §12651(a)(7) prohibits a person from knowingly making, using, or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money to the state.

E. COUNT FIVE

Violations of the Delaware FCA by Defendants

131. Defendants violated the Delaware FCA in the following respects:

a. The Defendants violated the Delaware FCA §1201(a)(1) by knowingly presenting or causing to be presented to an officer or employee of the State of Delaware a false or fraudulent claim for payment or approval;

b. Defendants violated Delaware FCA §1201(a)(2) by knowingly making,

using or causing to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State of Delaware;

c. Defendants violated Delaware FCA §1201(a)(3) by conspiring to defraud the State of Delaware by getting a false or fraudulent claim allowed or paid;

d. Defendants violated Delaware FCA §1201(a)(7) by knowingly making, using or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Delaware.

F. COUNT SIX

Violations of the Florida FCA by Defendants

132. Defendants violated the Florida FCA in the following respects:

a. Defendants violated §68.082(2)(a) by knowingly presenting or causing to be presented to an officer or employee of the State of Florida a false or fraudulent claim for payment or approval;

b. Defendants violated §68.082(2)(b) by knowingly making, using or causing to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State of Florida;

c. Defendants violated §68.082(2)© by conspiring to defraud the State of Florida by getting a false or fraudulent claim allowed or paid;

d. Defendants violated §68.082(2)(g) by knowingly making, using or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Florida.

G. COUNT SEVEN

Violations of the Georgia FCA by Defendants

133. Defendants violated the Georgia FCA in the following respects:

a. Defendants violated O.C.G.A. §49-4-168.1(a)(1) by knowingly presenting or causing to be presented to an officer or employee of the State of Georgia a false or fraudulent claim for payment or approval;

b. Defendants violated O.C.G.A. §49-4-168.1(a)(2) by knowingly making, using or causing to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State of Georgia;

c. Defendants violated O.C.G.A. §49-4-168.1(a)(3) by conspiring to defraud the State of Georgia by getting a false or fraudulent claim allowed or paid;

d. Defendants violated O.C.G.A. §49-4-168.1(a)(7) by knowingly making, using or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Georgia.

H. COUNT EIGHT

Violations of the Hawaii FCA by Defendants

134. Defendants violated the Hawaii FCA in the following respects:

a. Defendants violated H.R.S. Section 661.21(a)(1) by knowingly presenting or causing to be presented to an officer or employee of the State of Hawaii a false or fraudulent claim for payment or approval;

b. Defendants violated H.R.S. Section 661.21(a)(2) by knowingly making,

using or causing to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State of Hawaii;

c. Defendants violated H.R.S. Section 661.21(a)(3) by conspiring to defraud the State of Hawaii by getting a false or fraudulent claim allowed or paid;

d. Defendants violated H.R.S. Section 661.21(a)(7) by knowingly making, using or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Hawaii.

I. COUNT NINE

Violations of the Illinois FCA by Defendants

135. Defendants violated the Illinois FCA in the following respects:

a. Defendants violated 740 ILCS 175/3(a)(1)(A) by knowingly presenting or causing to be presented to an officer or employee of the State of Illinois a false or fraudulent claim for payment or approval;

b. Defendants violated 740 ILCS 175/3 (a)(1)(B) by knowingly making, using or causing to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State of Illinois;

c. Defendants violated 740 ILCS 175/3 (a)(1)© by conspiring to commit a violation of subparagraphs (A), (B), or (G);

d. Defendants violated 740 ILCS 175/3 (a)(1)(G) by knowingly making, using or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Illinois.

J. COUNT TEN

Violations of the Indiana FCA by Defendants

136. Defendants violated the Indiana FCA in the following respects:

a. Defendants violated I.C.5-11-5.5-2(b)(1) by knowingly presenting a false claim to the State of Indiana for payment or approval;

b. Defendants violated I.C. 5-11-5.5-2(b)(6) by knowingly making or using a false record or statement to obtain payment or approval of a false claim from the State of Indiana;

c. Defendants violate I.C. 5-11-5.5-2 (b)(6) by making or using a false record or statement to avoid an obligation to pay the State of Indiana.

d. Defendants violated I.C. 5-11-5.5-2 (b)(7) by knowingly conspiring with another person to perform any of those acts described in (a), (b), and © above.

K. COUNT ELEVEN

Violations of the Louisiana FCA by Defendants

137. Defendants violated the Louisiana FCA in the following respects:

a. Defendants violated RS 46:438.3A by knowingly presenting or causing to be presented a false or fraudulent claim;

b. Defendants violated RS 46:438.3B by knowingly engaging in misrepresentation or making, using, or causing to be made or used, a false record or statement to obtain payment for a false or fraudulent claim from the Louisiana Medicaid program;

c. Defendants violated RS 46:438.3C by knowingly making, using, or caused to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay money to the Louisiana Medicaid program;

d. Defendants violated RS 46:438.3D by conspiring to defraud, or attempt to defraud, the Louisiana Medicaid program through misrepresentation or by obtaining, or attempting to obtain, payment for a false or fraudulent claim;

e. Defendants violated RS 46.438.2A(2) by soliciting, receiving, offering, or paying remuneration, including but not limited to kickbacks, bribes, rebates, directly or indirectly, overtly or covertly, in cash or in kind, in return for purchasing, leasing, or ordering, any good, supply, service or facility for which payment may be made, in whole or in part, under the Louisiana Medicaid program.

L. COUNT TWELVE

Violations of the Michigan FCA by Defendants

138. Defendants violated the Michigan FCA in the following respects:

a. Defendants violated MCL 400.607(1) by knowingly presenting or causing to be presented to an officer or employee of the State of Michigan a claim under the social welfare act, upon or against the state, knowing the claim to be false;

b. Defendants violated MCL 400.604 by knowingly soliciting, offering, or receiving a kickback or bribe in connection with the furnishing of goods or services for which payment is or may be made in whole or in part pursuant to a program established under Act No. 280 of the Public Acts of 1939, as amended;

c. Defendants violated MCL 400.606(1) by entering into an agreement, combination, or conspiracy to defraud the state by obtaining or aiding another to obtain the payment or allowance of a false claim under the social welfare act;

d. Defendants violated MCL 400.607(3) by knowingly making, using or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Michigan pertaining to a claim presented under the social welfare act.

M. COUNT THIRTEEN

Violations of the Montana FCA by Defendants

139. Defendants violated the Montana FCA in the following respects:

a. Defendants violated MCA 17-8-403(1)(a) by knowingly presenting or causing to be presented to an officer or employee of the State of Montana a false or fraudulent claim for payment or approval;

b. Defendants violated MCA 17-8-403(1)(b) by knowingly making, using or causing to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State of Montana;

c. Defendants violated MCA 17-8-403(1)© by conspiring to commit a violation of subparagraphs (a), (b), or (g);

d. Defendants violated MCA 17-8-403(1)(g) by knowingly making, using or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Montana.

N. COUNT FOURTEEN

Violations of the Nevada FCA by Defendants

140. Defendants violated the Nevada FCA in the following respects:

a. Defendants violated NRS 357.040(1)(a) by knowingly presenting or causing to be presented a false or fraudulent claim for payment or approval;

b. Defendants violated NRS 357.040(1)(b) by knowingly making, using or causing to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State of Nevada;

c. Defendants violated NRS 357.040(1)© by conspiring to commit a violation of subparagraphs (a), (b), or (g);

d. Defendants violated NRS 357.040(1)(g) by knowingly making, using or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Nevada.

O. COUNT FIFTEEN

Violations of the New Jersey FCA by Defendants

141. Defendants violated the New Jersey FCA in the following respects:

a. violated the New Jersey FCA §2A:32C-3a by knowingly presenting or causing to be presented to an officer or employee or agent of the State of New Jersey, or to any contractor, grantee, or other recipient of State funds, a false or fraudulent claim for payment or approval;

b. Defendants violated New Jersey FCA §2A:32C-3b by knowingly

making, using or causing to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State of New Jersey;

c. Defendants violated New Jersey FCA §2A:32C-3c by conspiring to defraud the State by getting a false or fraudulent claim allowed or paid by the State;

d. Defendants violated New Jersey FCA §2A:32C-3g by knowingly making, using or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State.

P. COUNT SIXTEEN

Violations of the New Mexico FCA by Defendants

142. Defendants violated the New Mexico FCA in the following respects:

a. violated NMSA §27-14-4A by presenting or causing to be presented to the state a claim for payment under the Medicaid program knowing that such claim is false or fraudulent;

b. Defendants violated NMSA §27-14-4C by making, using or causing to be made or used a false record or statement to obtain a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false;

c. Defendants violated NMSA §27-14-4D by conspiring to defraud the state by getting a claim allowed or paid under the Medicaid program knowing that such claim is false or fraudulent;

d. Defendants violated NMSA §27-14-4E by knowingly making, using or

causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State, relative to the Medicaid program, knowing that such record or statement is false.

Q. COUNT SEVENTEEN

Violations of the New York FCA by Defendants

143. The Defendants violated the New York FCA in the following respects:

a. The Defendants violated State Fin. Law §189.1(a) by knowingly presenting or causing to be presented a false or fraudulent claim for payment or approval;

b. The Defendants violated State Fin. Law §189.1(b) by knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim;

c. The Defendants violated State Fin. Law §189.1© by conspiring to commit a violation paragraph (a), (b) or (g) of this subdivision;

d. The Defendants violated State Fin. Law §189.1(g) by knowingly making, using or causing to be made or used a false record or statement material to an obligation to pay or transmit money or property to the state.

R. COUNT EIGHTEEN

Violations of the Oklahoma FCA by Defendants

144. Defendants violated the Oklahoma FCA in the following respects:

a. Defendants violated Okla. Stat. §63-5053.1(B)(1) by knowingly presenting or causing to be presented to an officer or employee of the State of Oklahoma, a false or fraudulent claim for payment or approval;

b. Defendants violated Okla. Stat. §63-5053.1(B)(2) by knowingly making, using or causing to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the state;

c. Defendants violated Okla. Stat. §63-5053.1(B)(3) by conspiring to defraud the state by getting a false or fraudulent claim allowed or paid;

d. Defendants violated Okla. Stat. §63-5053.1(B)(7) by knowingly making, using or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state.

S. COUNT NINETEEN

Violations of the Rhode Island FCA by Defendants

145. Defendants violated the Rhode Island FCA in the following respects:

a. Defendants violated R.I. Gen. Laws § 9-1.1-3(a)(1) by knowingly presenting or causing to be presented to an officer or employee of the state or member of the guard a false or fraudulent claim for payment or approval;

b. Defendants violated R.I. Gen. Laws § 9-1.1-3(a)(2) by knowingly making, using or causing to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the state;

c. Defendants violated R.I. Gen. Laws § 9-1.1-3(a)(3) by conspiring to defraud the state by getting a false or fraudulent claim allowed or paid;

d. Defendants violated R.I. Gen. Laws § 9-1.1-3(a)(7) by knowingly making, using or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state.

T. COUNT TWENTY

Violations of the Tennessee FCA by Defendants

146. Defendants violated the Tennessee FCA in the following respects:

a. Defendants violated Tenn. Code Ann. §71-5-181(a)(1)(A) by presenting or causing to be presented to the state a claim under the Medicaid program knowing such claim is false or fraudulent;

b. Defendants violated Tenn. Code Ann. §71-5-181(a)(1)(B) by making, using or causing to be made or used, a record or statement to get a false or fraudulent claim under the Medicaid program paid or approved by the state knowing such record or statement is false;

c. Defendants violated Tenn. Code Ann. §71-5-181(a)(1)© by conspiring to defraud the state by getting a claim allowed or paid under the Medicaid program knowing such claim is false or fraudulent;

d. Defendants violated Tenn. Code Ann. §71-5-181(a)(1)(D) by making, using or causing to be made or used, a record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state, relative to the Medicaid program, knowing such record or statement is false.

U. COUNT TWENTY ONE

Violations of the Texas FCA by Defendants

147. Defendants knowingly or intentionally reported to the State of Texas' Medicaid Program false statements or misrepresentations regarding their pharmaceutical products. These actions were repeated and continuous violations of the Texas Medicaid Fraud Prevention Act ("TMFPA").

148. Defendants violated the TMFPA in the following respects:

a. Section 36.002(1) prohibits a person from knowingly or intentionally making or causing to be made a false statement or misrepresentation of material fact on an application for a contract, benefit, or payment under the Medicaid Program; or that is intended to be used to determine a person's eligibility for a benefit or payment under the Medicaid program;

b. Section 36.002(2) prohibits a person from knowingly or intentionally concealing or failing to disclose an event that permits a person to receive a benefit or payment that is not authorized, or that permits a person to receive a benefit or payment that is greater than the benefit or payment that is authorized;

c. Section 36.002(4) prohibits a person from knowingly or intentionally making or causing to be made a false statement or misrepresentation of fact concerning information required to be provided by a federal or state law, rule, regulation or provider agreement pertaining to the Medicaid Program;

d. Section 36.002(5) prohibits a person, except as authorized under the Medicaid program, from knowingly paying, charging, soliciting, accepting, or receiving,

in addition to an amount paid under the Medicaid program, a gift, money, a donation, or other consideration as a condition to the provision of a service or product or the continued provision of a service or product if the cost of the service or product is paid for, in whole or in part, under the Medicaid program; and

e. Section 36.002(9) prohibits a person from knowingly entering into an agreement, combination, or conspiracy to defraud the state by obtaining or aiding another person in obtaining an unauthorized payment or benefit from the Medicaid program or a fiscal agent.

V. COUNT TWENTY TWO
Violations of the Wisconsin FCA by Defendants

149. Defendants violated the Wisconsin FCA in the following respects:

a. Defendants violated Wis. Stat. §20.931(2)(a) by knowingly presenting or causing to be presented to an officer, employee, or agent of the state a false claim for medical assistance;

b. Defendants violated Wis. Stat. §20.931(2)(b) by knowingly making, using or causing to be made or used a false record or statement to get a false claim paid for medical assistance;

c. Defendants violated Wis. Stat. §20.931(2)© by conspiring to defraud the state by obtaining allowance or payment of a false claim for medical assistance or by knowingly making or using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Medical Assistance program;

d. Defendants violated Wis. Stat. §20.931(2)(g) by knowingly making,

using or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Medical Assistance program.

W. COUNT TWENTY THREE

Violations of the Massachusetts FCA by Defendants

150. Defendants violated the Massachusetts FCA in the following respects:

a. Defendants violated Mass. Gen. Laws Ch. 12, §5B(1) by knowingly presenting or causing to be presented a false claim for payment or approval;

b. Defendants violated Mass. Gen. Laws Ch. 12, §5B(2) by knowingly making, using or causing to be made or used a false record or statement to obtain payment or approval of a claim by the commonwealth;

c. Defendants violated Mass. Gen. Laws Ch. 12, §5B(3) by conspiring to defraud the commonwealth through the allowance or payment of a fraudulent claim;

d. Defendants violated Mass. Gen. Laws Ch. 12, §5B(8) by knowingly making, using or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the commonwealth.

X. COUNT TWENTY FOUR

Violations of the Virginia FCA by Defendants

151. Defendants violated the Virginia FCA in the following respects:

a. Defendants violated Code of Virginia § 8.01-216.3A(1) by knowingly presenting, or causing to be presented, to an officer or employee of the Commonwealth

a false claim for payment or approval;

b. Defendants violated Code of Virginia § 8.01-216.3A(2) by knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Commonwealth;

c. Defendants violated Code of Virginia § 8.01-216.3A(3) by conspiring to defraud the Commonwealth by getting a false or fraudulent claim allowed or paid;

d. Defendants violated Code of Virginia § 8.01-216.3A(7) by knowingly making, using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Commonwealth.

Y. COUNT TWENTY FIVE

Violations of the District of Columbia FCA by Defendants

152. Defendants violated the District of Columbia FCA in the following respects:

a. Defendants violated D.C. Code Ann., 2-308.14(a)(1) by knowingly presenting, or causing to be presented, to an officer or employee of the District a false claim for payment or approval;

b. Defendants violated D.C. Code Ann., 2-308.14(a)(2) by knowingly making, using, or causing to be made or used, a false record or statement to get a false claim paid or approved by the District;

c. Defendants violated D.C. Code Ann., 2-308.14(a)(3) by conspiring to defraud the District by getting a false claim allowed or paid by the District;

d. Defendants violated D.C. Code Ann., 2-308.14(a)(7) by knowingly

making, using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the District.

Z. COUNT TWENTY SIX

Violations of the Chicago FCA by Defendants

153. Defendants violated the Chicago FCA in the following respects:

a. Defendants violated Mun. Code of Chicago 1-22-020(1) by knowingly presenting, or causing to be presented, to an official or employee of the city a false or fraudulent claim for payment or approval;

b. Defendants violated Mun. Code of Chicago 1-22-020(2) by knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the District;

c. Defendants violated Mun. Code of Chicago 1-22-020(3) by conspiring to defraud the District by getting a false claim allowed or paid by the city;

d. Defendants violated Mun. Code of Chicago 1-22-020(7) by knowingly making, using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the city.

AA. COUNT TWENTY SEVEN

Violations of the City of New York's FCA by Defendants

154. The Defendants violated the City of New York's FCA in the following respects:

a. The Defendants violated New York City Administrative Code § 7-

803(a)(1) by knowingly presenting, or causing to be presented, to an city officer or employee a false claim for payment or approval by the city;

b. The Defendants violated New York City Administrative Code § 7-803(a)(2) by knowingly making, using, or causing to be made or used, a false record or statement to get a false claim paid or approved by the city;

c. The Defendants violated New York City Administrative Code § 7-803(a)(3) by conspiring to defraud the District by getting a false claim allowed or paid by the city;

d. The Defendants violated New York City Administrative Code § 7-803(a)(7) by knowingly making, using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease, directly or indirectly, an obligation to pay or transmit money or property to the city.

IX. DAMAGES

155. The measure of damages the United States is entitled to recover under the FCA is the amount of money the government paid out by reason of the false claims over and above what it would have paid out if the claims had not been false or fraudulent. *Marcus,* 317 U.S. at 543-545, 63 S.Ct. 379; *United States v. Neifert-White,* 390 U.S. at 232, 88 S.Ct. 959. The government is allowed to recover three times the amount of its damages. 31 U.S.C. § 3729(a). "FCA damages 'typically are liberally calculated to ensure that they afford the government complete indemnity for the injuries done it.' " *United States ex rel. Roby v. Boeing Co.,* 302 F.3d 637, 646 (6th Cir.2002) (quoting *United States ex rel. Compton v. Midwest Specialties, Inc.,* 142 F.3d 296, 304

(6th Cir.1998)).

156. The computation of damages does not have to be done with mathematical precision but, rather, may be based upon a reasonable estimate of the loss. The government is entitled to recover a civil penalty for each false claim. Each knowing submission of a false or fraudulent claim is a separate violation of the False Claims Act. 31 U.S.C. § 3729(a)(2). Thus, the number of violations of the False Claims Act depends on the number of false or fraudulent claims or other requests for payments that defendant caused to be submitted. A penalty is assessed per false claim. *See United States v. Bornstein,* 423 U.S. 303, 313, 96 S.Ct. 523, 46 L.Ed.2d 514 (1976); *United States v. Killough,* 848 F.2d 1523, 1533 (11th Cir.1988) (holding that each separate fraudulent submission by a defendant demanding payment by the government is a "claim" within the meaning of the FCA).

157. The penalty is mandatory. See United States v. Hughes, 585 F.2d 284, 286 (7th Cir.1978); *Killough,* 848 F.2d at 1533-34. As the legislative history to the 1986 Amendments to the FCA explains:

> The imposition of this forfeiture is automatic and mandatory for each claim which is found to be false. The United States is entitled to recover such forfeiture solely upon proof that false claims were made, without proof of any damages.... A forfeiture may be recovered from one who submits a false claim even though no payments were made on the claim. S.Rep. No. 345, 99th Cong., 2d Sess. at 8 (July 28, 1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5273 (internal citation omitted).

158 The United States does not need to prove actual damages in order to recover these statutory penalties. The United States may recover penalties upon a showing that the claims were false, even if no damage is proved. *Varljen v. Cleveland Gear Co., Inc.,* 250 F.3d 426, 429 (6th Cir.2001) ("recovery under the FCA is not

dependent upon the Government's sustaining monetary damages"); *see also United States ex rel. Hagood v. Sonoma County Water Agency,* 929 F.2d 1416, 1421 (9th Cir.1991) ("No damages need be shown in order to recover the penalty") (citing *721 *Rex Trailer Co. v. United States,* 350 U.S. 148, 153 n. 5, 76 S.Ct. 219, 100 L.Ed. 149 (1956).

X. RELIEF REQUESTED

159. Relator requests the following relief be imposed against Defendants:

(a) That the United States be awarded three times the amount of damages which it sustained because of the acts of Defendants pursuant to §3729(a)(1)(2) and (3) of the FCA; that the States of California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Michigan, Montana, Nevada, New Jersey, New Mexico, New York, Oklahoma, Rhode Island, Tennessee, Texas, Wisconsin, the Commonwealths of Massachusetts and Virginia, the District of Columbia, and the Cities of Chicago and New York be awarded three times the amount of any payments provided under their Medicaid programs as a result of Defendants' unlawful acts, pursuant to the respective provision of each State FCA;

(b) That Defendants each be held liable for civil penalties of up to $11,000.00, but not less than $5,500.00 to the U.S. for each and every act in violation of the FCA; that the Defendants each be held liable for civil penalties applicable for each and every unlawful act in violation of each respective State FCA;

© That this Court award such interest as is available pursuant to the FCA and/or each State FCA;

(d) That in the event the United States intervenes in this action and takes over its

prosecution, the Relator be awarded an amount for bringing this action on behalf of the United States of at least 15% but not more than 25% of the proceeds paid to the United States resulting from the trial or settlement of the claim, pursuant to §3730(d)(1) of the FCA; that in the event any State intervenes in this action and takes over its prosecution, the Relator be awarded an amount for bringing this action for that respective State equal to a percentage of the proceeds paid to that State resulting from the trial or settlement of the claim, pursuant to the applicable provision of that State FCA;

(e) That in the event the United States does not intervene in this action, the Relator be awarded an amount for bringing this action for the United States of at least 25% but not more than 30% of the proceeds paid to the United States resulting from the trial or settlement of the claim, pursuant to §3730(d)(2) of the FCA; that in the event a State does not intervene in this action, the Relator be awarded an amount for bringing this action for each respective State equal to a percentage of the proceeds paid to that State resulting from the trial or settlement of the claim, pursuant to the applicable provision of that State's FCA;

(f) That this Court award reasonable attorneys' fees, costs and expenses to the Relator, which were necessarily incurred in bringing and prosecuting this case, pursuant to §3730(d)(1) or (2) of the FCA and each respective State FCA; and

(g) That this Court award such other relief as it deems just, necessary and fair.

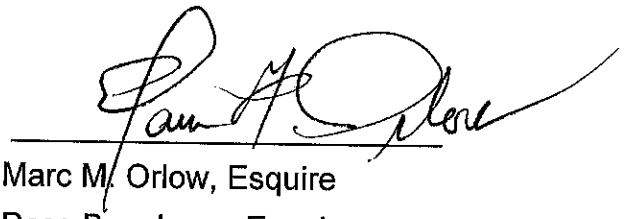
JURY DEMAND

Relator requests a trial by jury of all issues so triable.

DATED: January 27, 2014

Respectfully submitted,

Counsel for Plaintiff/Relator



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